C. Benefits and Beneficiary Protections

1. Introduction

Subpart C of these regulations details the scope of benefits a Medicare beneficiary is entitled to receive when electing coverage through an M+C plan, as well as establishing a number of beneficiary protections in areas related to access rules, enrollee notification requirements, confidentiality and others. The statutory authority for most of the provisions of subpart C is found in section 1852 of the Act, which outlines benefit requirements and provides authority for beneficiary protections under Medicare Part C. Many of the statutory provisions are the same as, or similar to, benefit provisions of section 1876 of the Act. Therefore, much of the regulatory language of part 417 is retained for purposes of establishing M+C standards, as provided for in section 1856(b)(2) of the Act (which provides for basing M+C standards on section 1876 standards implementing analogous provisions, where consistent with Part C).

All M+C organizations are required to cover the full range of Medicare benefits that are available under original Medicare to beneficiaries in the area who are not enrolled in an M+C plan, subject to certain rules regarding an accessible network of providers. M+C organizations are further required to cover Medicare preventive benefits with the same frequency that they are covered under original Medicare (for example, annual

screening mammography examinations). Beneficiaries may be required to contribute to the cost of covered services in the form of cost sharing provided for under the M+C plan. Beneficiaries may have to cover all costs until a deductible is met (including the high deductible provided for under an MSA plan--see section III of this preamble), a percentage of costs in the form of coinsurance, or a fixed amount for services, in the form of a copayment. As discussed in section II.G below, there are limits that apply to the cost sharing that can be imposed on beneficiaries under M+C plans. For benefits that are covered under original Medicare, the benefits must be obtained through providers meeting the conditions of participation of the Medicare program.

This section of the preamble mainly discusses the requirements for network plans. Sections III and IV of the preamble provide more extensive information about benefit requirements applicable to non-network M+C MSA plans and to private fee-for-service plans, respectively. Organizations with network plans, which include coordinated care plans and network M+C MSA plans, are permitted to restrict enrollees to a specified network of providers in the case of non-emergency/urgent services if they have a network in place to provide these services directly or through arrangements (that is, written agreements with providers) that meet the availability and accessibility

requirements of section 1852(d)(1) of the Act and §422.112, discussed below.

2. Emergency, Urgently Needed, and Post-Stabilization Care Services (§§422.2, 422.100, 422.112, and new §422.113)

In some situations, an M+C organization is required to assume liability for services provided to Medicare enrollees through noncontracting providers. In particular, under §422.100(b), the organization is required to assume financial responsibility for the following items and services obtained from a provider that does not contract with the M+C organization:

- Emergency services;
- Urgently needed services;
- Renal dialysis services provided while the enrollee was temporarily outside the M+C plan's service area;
- Post-stabilization care services; and
- For both network and non-network plans, services denied by the M+C organization and found upon appeal (under subpart M of this part) to be services the enrollee was entitled to have furnished or paid for by the M+C organization.

The requirements that the M+C organization assume financial liability for renal dialysis services and post-stabilization care are new requirements introduced by the BBA that were not included in the requirements of section 1876 of the Act. The definitions of emergency services and urgently needed services in the M+C

regulations are based on section 1852(d) of the Act, and thus differ from those used under the previous Medicare managed care program (see §417.401). In accordance with section 1852(d)(3) of the statute, an "emergency medical condition" exists if a "prudent layperson" could reasonably expect the absence of immediate medical attention to result in serious jeopardy or harm to the individual. In addition, the new definition of "emergency services" includes emergency services provided both within and outside of the plan, while the definition of "urgently needed services" continues to encompass only services provided outside of the plan's service area (or continuation area, if applicable), except in extraordinary circumstances (as discussed below). Under section 1852(d)(1)(C)(i) of the Act, M+C organizations are required to pay for nonemergency services provided other than through the organization where the services are immediately required because of unforseen illness, injury or condition, and it is not reasonable given the circumstances to obtain the services through the organization.

In the June 26, 1998 interim final rule, definitions of emergency services and urgently needed services were provided at §422.2; financial responsibility of the M+C organization for emergency, urgently needed, and post-stabilization care services provided outside of the organization was addressed at §422.100; and special coverage rules for emergency services and urgently

needed services were provided at §422.112. In this final rule, general requirements for financial responsibility for services provided outside the M+C organization remain at §422.100, while definitions and policies relating to all types of emergency episodes of care, including ambulance services, emergency services, urgently needed services, and post-stabilization care services, have been consolidated at §422.113. Comments on these aspects of the subpart C regulations are discussed below.

a. Definitions (§422.2 and new §422.113)

Comment: Two commenters requested that we specify in the definition of "urgently needed services" that these are not "emergency services."

Response: Section 1852(d)(1)(C)(i) of the Act specifies that urgently needed services are not emergency services. Thus, as the commenters suggested, we are revising the definition of urgently needed services to include the requested clarification.

Comment: One commenter expressed support for, while another commenter opposed, the inclusion of in-area unusual events in the definition of urgently needed services. The commenter opposing the inclusion of in-area urgently needed services suggested that if this provision is retained, M+C organizations should not be required to disclose it in member materials or that we give examples of circumstances in which this exception would apply. One commenter asked if this meant that beneficiaries could

unilaterally obtain care out-of-plan if their M+C organization did not provide the care they requested. The commenter supporting our position provided the example of equipment failure as a case in which in-area services might not be available.

Response: As discussed in the preamble to the June 26, 1998 interim final rule (63 FR 34973), the inclusion of in-area unusual events in the definition of urgently needed services is based on the statutory language at section 1852(d)(1)(C)(i) of the Act, which does not specify that these services are covered only when the beneficiary is out-of-area. Rather, the statute provides for coverage of urgently needed services when "it was not reasonable given the circumstances to obtain the services through the organization." As stated in the regulations, in-area coverage of urgently needed services applies only under unusual and extraordinary circumstances, for services provided when the enrollee is in the service or continuation area, but the organization's provider network is temporarily unavailable or inaccessible, and such services are medically necessary and immediately required. We believe that examples of when this could arise would include unusual events such as an earthquake or strike, if such events impede enrollee access to care through M+C plan providers. This regulatory definition of urgently needed services should be used in any materials that include a description of urgently needed services.

With regard to the request that the in-area exception in the definition of urgently needed services be interpreted to mean that beneficiaries could seek care out-of-plan if the particular services are not provided by an M+C organization, we believe that the commenter is asking about situations where an M+C organization has made a judgment that services are not necessary or not covered, rather than one in which the network is unavailable. There are other mechanisms in place to handle such situations. We may require a plan to take corrective action, where necessary, if a plan fails to provide services. In addition, services that the beneficiary believes he or she was entitled to receive from the M+C organization, but that the organization denied or otherwise did not provide, may be appealed under the regulations in subpart M of part 422. Whether situations involving equipment failures would be considered urgently needed services depends upon the clinical condition of the patient, and the M+C organization's ability to make services available notwithstanding the equipment failure.

We note that, inherent to the various requirements under §422.112 relating to an M+C organization's responsibility to provide adequate access to covered services, is the obligation of an M+C organization to provide access to necessary care through out-of-network specialists when its network is inadequate or unavailable. That is, if in an individual case a plan's provider

network is not adequate to meet an enrollee's health care needs (for example, the plan includes no specialist qualified to treat an enrollee's rare condition), the organization shall authorize the individual to go out of network to obtain the necessary care. We are revising §422.112(a)(3) to make this requirement explicit. As discussed in detail in section II.M.9 of this preamble, failure to authorize such care constitutes an adverse organization determination, with concomitant appeal rights.

Comment: One commenter requested further elaboration on what is meant by "prudent layperson" within the definition of emergency services.

Response: Section 1852(d)(3) of the Act provides the definition of emergency services that includes the prudent layperson standard. Specifically, section 1852(d)(3)(B) of the Act states that an emergency medical condition is a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in (i) placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy, (ii) serious impairment to bodily functions, or (iii) serious dysfunction of any bodily organ or part. This entire definition should be considered when

making a determination of whether a beneficiary acted appropriately in seeking emergency care. This definition is what the independent review entity under contract with us will consider when making determinations on beneficiary appeals of emergency services that an M+C organization has denied. With respect to the term "prudent layperson," we believe that the term "prudent" has a commonly understood meaning, and would refer the reader to the general dictionary definition of this term. A layperson refers to an individual with an average knowledge of health and medicine, as the definition of "emergency medical condition" states. We do not believe that further elaboration of the term prudent layperson is necessary.

b. Enforcement of Emergency Requirements (§§422.80, 422.100, 422.113)

Comment: Commenters requested clarification of what steps we were taking to ensure that M+C organizations provide access to emergency services intended by law.

Response: One mechanism we use to ensure appropriate provision of covered services by M+C organizations is a review process of all organization materials provided to beneficiaries, including both pre-enrollment marketing materials provided to prospective enrollees and post-enrollment member materials for enrollees. For example, §422.80(b)(5)(v) lists examples of membership communication materials we review, including

membership rules, subscriber agreements (evidence of coverage), and member handbooks. In considering our response to this comment, we have determined that "wallet-sized" instruction cards that might be used in the case of an emergency should also be expressly included as materials to be reviewed, because these cards may contain instructions to enrollees on how to access care, including instructions on what to do in an emergency. We, therefore, are adding wallet card instructions to the list of examples of marketing materials to be reviewed under §422.80(b)(5)(v) to ensure that wallet card instructions to enrollees are consistent with the statute and regulations, particularly requirements that apply to emergency and urgently needed services. We note that, as part of our monitoring of the "prudent layperson" standard, we have asked our independent review entity to report, on a quarterly basis, each instance in which it overturns a denial of a claim for emergency services.

Also in response to this comment, we have decided to specify at §422.100(b)(1)(i) that M+C organizations are required to cover ambulance services provided other than through the organization that are dispatched through 911 or its local equivalent. Section 422.113 specifies that the M+C organization bears financial responsibility for ambulance services where other means of transportation would endanger the beneficiary’s health. This policy is consistent with original Medicare’s coverage of

ambulance services where other means of transportation would endanger the health of the beneficiary as provided by section 1861(s)(7) of the Act, as well as with the emergency coverage provisions of section 1852(c)(1)(E) of part C of the Act. In particular, we believe that the law's reference to use of the 911 telephone system indicates statutory intent for coverage of ambulance services whether provided through the organization or other than through the organization. Ambulance services provided through the organization would also be considered part of basic benefits under §§422.100(a) and 422.101. We note that nonemergency ambulance services generally would be covered only when provided through the organization, to the same extent the services are covered under the general Medicare principles set forth in section 1861(s)(7) of the Act (that is, when use of other forms of transportation would endanger the health of the beneficiary.) Regulations on original Medicare coverage of ambulance services may be found at §410.40.

c. Access to Emergency and Urgently Needed Services (§§422.112(c) and 422.113).

Comment: Commenters generally supported emergency services policies, such as the prudent layperson definition, the prohibition of prior authorizations, the requirement for out-of-plan coverage, and the requirement that the treating physician determine when the patient is stable. Commenters

requested clarification of the prohibition on prior authorization.

Response: In considering our policy prohibiting prior authorization for emergency services as required under section 1852(d)(1)(E) of the Act, we have determined that the regulations should expressly reflect the fact that two parties are protected from prior authorization requirements, that is, the beneficiary and the emergency provider treating the beneficiary. We are clarifying at §422.113(b)(2)(ii)(A) that prior authorization may not be required from the beneficiary in any materials furnished to enrollees (including wallet card instructions) and that, consistent with section 1852(c)(1)(E) of the Act, disclosure of an enrollee's right to coverage of services must include disclosure of the enrollee’s right to use the 911 telephone system. Also, §422.113(b)(2)(ii)(B) specifies that materials furnished to providers (including contracts with providers) may not include instructions to seek prior authorization before an enrollee has been stabilized.

We believe that these clarifications will promote compliance with the prohibition in section 1852(d)(1)(E) of the Act on prior authorization requirements for emergency services.

Comment: A commenter requested that we specify that retroactive denials should not be allowed based solely on a final

diagnosis, and that the presenting condition from the perspective of the prudent layperson should determine coverage.

Response: As noted in our preamble discussion of the provisions of §422.112 in the June 26, 1998 interim final rule, long-standing Medicare managed care manual policy (§2104) prohibited retrospective denial for services that appeared to be emergencies, but turned out not to be emergency in nature. This policy is consistent with the "prudent layperson" element of the definition of an emergency medical condition, in that the perspective of the enrollee is a significant factor in determining whether an enrollee acted appropriately in seeking emergency care. As explained in the preamble to the interim final rule, we believe that the current regulations already require such coverage. However, in light of the commenter's concern, we are including in new §422.113(b)(2)(iii) the explicit requirement that M+C organizations assume financial responsibility for services meeting the prudent layperson standard in the definition of emergency medical condition, regardless of final diagnosis.

Comment: We received a number of comments regarding the limit in §422.112(c) on copayments for emergency services obtained outside the M+C plan's provider network (the lower of $50 or whatever the plan would charge for in-plan emergency care). Some commenters argued that significant copayments were

necessary to deter unnecessary visits to the emergency room, and noted that commercial fee-for-service insurance plans have copayments for emergency care that may be higher than the $50 limit. Other commenters thought the $50 limit was a reasonable standard. Some commenters suggested that the copayment for an emergency room visit should be higher than that for a physician office visit. One commenter requested that a requirement for advance disclosure of the emergency room copayment amount be substituted for a dollar limit. One commenter requested clarification that the $50 limit be for the "sum total" for all care received for the emergency episode. Another commenter argued for a rule prohibiting copayments altogether, or at least for a reduced limit for low-income beneficiaries.

Response: We appreciate the commenters' responses to our request for public comment on the policy of limiting the amount that can be imposed as a copayment for emergency services. As we stated in the preamble to the June 26, 1998 interim final rule, our data showed that only 7 percent of Medicare managed care plans were charging more than $50 for emergency services. We believe that all of the above comments have some merit, but that, on balance, retaining the current policy (the lower of $50 or whatever the plan would charge for in-plan emergency care) is the best course of action. Although we agree that copayments can effectively deter unnecessary use of services, we believe that a

$50 copayment accomplishes this objective, since 93 percent of M+C organizations do not exceed this amount. We also believe, however, that a copayment higher than this amount could potentially deter an enrollee from receiving necessary emergency services. M+C organizations retain flexibility to set copayment amounts up to $50, including possible consideration for low-income beneficiaries, and organizations may provide for a substantial differential between copayments for physician office visits and emergency room visits. We believe that the difference between a $50 copayment for an emergency room visit and the typical $5 to $10 copayment for a physician's office visit is sufficient incentive to receive nonemergency services at a physician's office. With respect to the commenter who advocated disclosure of emergency room copayments, such copayments are already disclosed in the MedicareCompare database on the Internet at HCFA's website, www.hcfa.gov, and M+C organizations are required to disclose these amounts in membership materials provided to beneficiaries. Finally, we believe that the current language already conveys that $50 is the sum total limit for copayment for services defined as emergency services, and that further clarification beyond this response is not necessary.

Comment: One commenter suggested that beneficiaries be issued a single Medicare identification card that could be presented to their treating physicians and staffs, rather than

one card issued by the M+C organization and one issued by Medicare. The commenter stated that beneficiaries frequently do not present the correct card denoting M+C plan coverage to their treating physicians. The commenters believe that the use of a single card would allow physicians and staffs to easily identify exact Medicare coverage and the appropriate administrative and billing procedures to be applied.

Response: The purpose of the Medicare card issued to the beneficiary is to serve as proof of entitlement to the Medicare program. We believe that the Medicare card and the M+C plan membership card serve two different purposes--to identify the individual as entitled to Medicare and to subsequently identify how the individual receives the services. Combining these elements into a single identification card would require the issuance of a new card each time the beneficiary chose a new plan or returned to original Medicare. Thus, although we welcome suggestions to improve the efficiency of our operations, we do not believe that a single card should be issued to the beneficiary.

(d. Post-Stabilization Care Services (§§422.100 and 422.113)

Section 1852 (d)(2) of the Act gives the Secretary express authority to establish requirements needed to promote the "efficient and timely coordination of appropriate maintenance and post-stabilization care" (hereafter together referred to as

"post-stabilization care"). Section 1852(d)(1)(C)(iii) of the Act establishes an M+C organization's responsibility to provide reimbursement for these services. Implementing regulations at §§422.100(b)(1)(iii) and 422.113(c) specify that an M+C organization is financially responsible for post-stabilization care services obtained within or outside of the M+C organization. This requirement applies both to services pre-approved by the organization and services that were not pre-approved, under certain circumstances, including situations where an M+C organization fails to respond within 1 hour to a request for pre-approval from a provider of post-stabilization care services (as discussed in detail below). We received a number of comments regarding this section.

In this final rule, the special rules for post-stabilization care services are included under new §422.113. The requirement for financial responsibility for post-stabilization care services provided outside the organization remains at §422.100.

Comment: One commenter stated that after stabilization of the emergent medical condition, no immediate health risks should exist. This commenter asked why there is a need to change the time frame for obtaining approval of post-stabilization care, which the commenter apparently believed was 48 hours. Several commenters responded favorably to the 1-hour window for responding to a request for authorization of post-stabilization

services, with one commenter suggesting that 30 minutes would be a better time frame.

Response: If no immediate health risks exist following an emergency episode, the patient would most likely be discharged. Post-stabilization care services are administered to ensure that the patient remains stabilized following an emergency episode. We agree with the majority of commenters who supported the 1-hour time frame. We believe that an untimely response to a request for post-stabilization care services would delay the delivery of these services, thereby compromising their effectiveness. We are not aware of the 48-hour time frame referenced by one commenter, as no such time frame exists under Medicare law.

Comment: Several commenters recommended that we require that the request for approval not be made until after the enrollee is stabilized, so that the organization will have the necessary information at its disposal. Commenters requested clarification as to what constitutes a response by the M+C organization to a call from the hospital. For instance, one commenter asked if an organization would be in compliance with the 1-hour rule if it calls back within the hour and states it needs more time to make a decision on post-stabilization care services. One of these commenters also stated that we should require that the emergency department treating the member contact the M+C organization within an hour of the point at which the

member is stabilized. Another asked how the emergency provider would be held accountable for notification to the M+C organization once the patient is stable.

Response: Section 1852 (d)(1)(E) of the Act states that the M+C organization must provide coverage for emergency services without regard to prior authorization or the emergency care provider's contractual relationship with the organization. Implicit in this requirement is the fact that the organization may not require the provider to call for approval of services prior to the point of stabilization. If the hospital chooses to notify the organization while the patient is still being stabilized, the organization will still need an update on the status of the patient at the point of stabilization, in order to make an informed decision. If the provider calls when the enrollee is stabilized, an organization which calls back within the hour should not need more time to make a decision. Therefore, we consider a response by the M+C organization to be when the M+C organization submits a decision to the provider about its request for post-stabilization care. While we believe it is reasonable to expect the emergency provider to contact the M+C organization within an hour of the point at which the member is stabilized, we do not believe that this final rule, which establishes and clarifies the requirements that M+C organizations must meet, is an appropriate vehicle to impose such a requirement

on hospitals. (We are considering including such a requirement in future hospital provider agreements with Medicare, however.) It is clearly in the hospital's best interest to contact the organization as soon as a patient is stabilized in order to ensure plan coverage of post-stabilization services furnished by the hospital. In addition, in order to be able to bill the beneficiary in circumstances where the plan is not liable for payment, the treating provider is expected to provide the stabilized patient with a notice of non-coverage, such as an Advance Beneficiary Notice.

Comment: A number of commenters asked for clarification of the definition of post-stabilization care services. The majority of these commenters requested that post-stabilization care services be linked to the emergency episode. Two commenters inquired if the term post-stabilization care replaces the pre-BBA term "follow-up" care, which includes only routine care following an out-of-area emergency medical episode.

Response: We agree that the concept of post-stabilization care services could be clarified further, and we have expanded on the definition, including the addition of language addressing services furnished while waiting for a response to a request for authorization from an M+C organization. We also agree with the commenter that post-stabilization services should be limited to services related to the emergency medical condition.

By post-stabilization care services, we generally mean covered services, related to an emergency episode, provided after the enrollee is considered to be stable (see new §422.113(c)). Under the post-stabilization provisions set forth in the interim final rule, "post-stabilization" services were limited to services authorized by the M+C organization or services furnished when the organization cannot be reached, or fails to respond to a request for authorization within an hour. This definition did not address services that may be required during that hour to keep the patient stabilized. We believe that it is necessary to ensure that the patient continues to receive necessary treatment during the 1-hour time frame when the provider waits for the organization to respond. These services consist of those necessary to maintain the stable condition achieved through previously administered emergency services. Any period of instability that rises to the level of an emergency medical condition that occurs during this time would be covered under §422.113(b).

Section 422.113(c) also establishes that if the M+C organization does not respond within the 1-hour time frame, the M+C organization cannot be reached, the treating physician can proceed with post-stabilization services that are administered not only to ensure stability, but also to improve or resolve the patient’s condition. When an M+C organization representative who

is a non-physician and the treating physician cannot reach agreement on a course of treatment, the M+C organization must allow the treating physician to speak with a plan physician. By allowing the treating physician to proceed with care of the patient in these cases, we are ensuring that M+C enrollees receive the same standard of timely care as beneficiaries under original Medicare.

Accordingly, the revised definition of post-stabilization care services at §422.113(c)(1) reads as follows:

"(c) Post-stabilization care services means covered services, related to an emergency medical condition, that are provided after the enrollee is stabilized in order to maintain the stabilized condition, or, under the circumstances described in paragraph (2)(iii) below, to improve or resolve the enrollee's condition."

Section 422.113(c)(2) then describes the M+C organization's financial responsibility for post-stabilization care services. Specifically, "the M+C organization is financially responsible (consistent with §422.214) for post-stabilization care services obtained within or outside of the M+C organization that are-- (i) Pre-approved by a plan provider or other M+C organization representative; (ii) Not pre-approved by a plan provider or other M+C organization representative, but administered to maintain the stabilized condition, within 1 hour of a request to the M+C

organization for pre-approval of further post-stabilization services; or (iii) Not pre-approved by a plan provider or other M+C organization representative, but administered to maintain, improve, or resolve the enrollee's stabilized condition if--

(A) The M+C organization does not respond to a request for pre-approval within 1 hour;

(B) The M+C organization cannot be contacted; or

(C) The M+C organization representative and the treating physician cannot reach an agreement concerning the enrollee's care and a plan physician is not available for consultation. In this situation, the treating physician may continue with the care of the patient until a M+C organization physician is reached or one of the criteria in §422.113 (c)(3) is met."

To further clarify the above requirements, consider the following example: a patient is brought to the emergency department with the preliminary diagnosis of a seizure. The patient is screened and receives services to stabilize his condition. Thus far, the services that the patient has received are emergency services under §422.113(b). Once the emergency room physician considers the patient stabilized, the M+C organization is notified of the need to consult a neurologist in order to proceed with relevant diagnostic tests to determine the cause of the seizure, and to treat the cause of the seizure definitively. While the emergency provider waits 1 hour for a

response from the organization, post-stabilization services necessary to maintain the stable condition achieved through previously administered emergency services are administered.

If the M+C organization responds within 1 hour, it can approve the request for additional post-stabilization services under §422.113(c)(2)(i) or make other arrangements for additional services. If the organization did not respond within the 1-hour time frame, if the organization could not be contacted, or if the organization representative and the treating physician could not reach an agreement and a plan physician was not available for consultation during the hour, the treating physician can proceed with post-stabilization services administered not only to maintain the stabilized condition, but to improve or resolve the patient's condition. Again, if the organization representative and the treating physician cannot reach an agreement, the M+C organization must give the treating physician the opportunity to speak with a plan physician concerning the care of the patient. If a plan physician responds to a request for consultation outside the one hour time frame, the plan physician and the treating physician are expected to execute a plan for safe transfer of responsibility of the patient.

Comment: One commenter sought clarification as to when the M+C organization's liability to pay ends. This commenter does not believe that the M+C organization physician should have to

"arrive," as stated in the preamble of the June 26, 1998 interim final rule, in order to terminate the organization's responsibility to pay. This commenter also recommended that we explicitly state that even if the M+C organization does not respond within the hour, once it does respond, it should have the absolute right to control the care that is given to the member.

Response: We agree that the issue of when the M+C organization's financial responsibility ends needs further clarification. We also agree that the physician should not have to arrive in person at the hospital in order to assume responsibility for his or her patient. Therefore, we are incorporating the following language into §422.113(c)(3): "The M+C organization's financial responsibility for post-stabilization care services it has not pre-approved ends when--(i) A plan physician with privileges at the treating hospital assumes responsibility for the enrollee's care; (ii) A plan physician assumes responsibility for the enrollee through transfer; (iii) An M+C organization representative and the treating physician reach an agreement concerning the enrollee's care; or,(iv) The enrollee is discharged."

We do not agree that the M+C organization should have the absolute right to control the care that is given to the member when it does eventually respond and the one hour time period has elapsed. For example, a late response could result in a scenario

where post-stabilization care services may have already started, and in such a situation, we believe that interruption of a procedure in progress in order to transfer the enrollee to another facility could be harmful to the member. The M+C organization is financially responsible for post-stabilization services until the M+C organization and the treating physician execute a plan for safe transfer of responsibility. Safe transfer of responsibility should occur with the needs and the condition of the patient as the primary concern, so that the quality of care the patient receives is not compromised.

Comment: Several commenters asked that HCFA clarify that only an M+C plan physician with privileges at the treating hospital may assume responsibility for the M+C plan enrollee’s care.

Response: Generally, only an M+C plan physician may assume long-term responsibility for care furnished to an enrollee of that M+C plan. However, if there are no M+C plan physicians with privileges at the treating hospital, we would expect the treating physician and the M+C organization to make arrangements for appropriate care to be provided. Thus, we do not agree that an M+C plan physician with privileges at the treating hospital must necessarily assume responsibility for a plan enrollee's care.

Comment: Several commenters asked that we address how disputes between M+C organizations and providers would be resolved. One commenter asked that we develop guidelines for notification of organizations. Another commenter wanted to know how we will determine if a call was made, or responded to within 1 hour, if the provider's and M+C organization's records do not agree. Still another commenter suggested a provision holding the patient harmless for disputes between M+C organizations and the emergency provider regarding post-stabilization benefits and coverage.

Response: We believe that providers and M+C organizations will develop methods of documentation to ensure that calls are made and received in a timely manner, so that the 1-hour response requirement can be met and the possibility of disputes can be minimized. We do not believe the development of guidelines by HCFA to be necessary or appropriate. Complaints and disputes are addressed in the HCFA monitoring process, and resolution would depend on the circumstances encountered. Ultimately, if agreement cannot be reached, a dispute over whether the conditions for M+C coverage for post-stabilization care services under §422.100 and §422.113 have been met could be resolved in an enrollee's appeal of the M+C organization's denial of payment for post-stabilization services, or an appeal by a provider if the provider agrees not to charge the enrollee. (We note that the

rules governing payment for services furnished by noncontracting providers would apply in post-stabilization cases, as set forth in §422.214 and discussed in detail in section II.E of this preamble. We have made this explicit at §422.113(c)(2).) Based on this comment, we agree that M+C enrollees should be protected from excessive charges for post-stabilization care services. Therefore, new §422.113(c)(2)(iv) provides that cost-sharing for post-stabilization care services must not exceed cost-sharing amounts for services obtained through the organization.

Comment: One commenter stated that if an enrollee is admitted to a hospital for services that are later determined not to be emergency services, the M+C organization has no obligation to pay for services that a provider asserts are for post-stabilization care. In addition, a commenter asked whether, if there is a denial of post-stabilization care services, the treating physician can be given the right to speak with an M+C plan physician regarding the patient. Another commenter recommended we add protections against denials of post-stabilization care services.

Response: Section 1852(d)(3) of the statute states that the M+C organization is responsible for services required to treat an emergency medical condition under the prudent layperson standard. Organizations are not responsible for care sought by the enrollee when this standard is not met. Post-stabilization services are

similarly covered only following treatment for an emergency (as noted above, we have revised the definition, at §422.113(c)(1), to make this explicit.) If the patient did meet the prudent layperson standard, but the condition did not turn out to be an actual threat to the health of the patient, the M+C organization would not be responsible for any services beyond those services provided as part of the medical screening to determine whether an emergency medical condition existed. In such a nonemergency situation, the treating physician is expected to provide the patient with an Advanced Beneficiary Notice (ABN) to inform the patient that further services will not be covered.

With respect to the comment concerning denials, if the organization representative and the treating physician cannot reach an agreement concerning the enrollee's care, the M+C organization must give the emergency physician an opportunity to consult with an M+C organization physician.

With respect to the request for further patient protections, as noted above, the enrollee (or, the provider, if the provider agrees not to charge the enrollee) has the right to appeal any decision by an M+C organization to deny payment for post-stabilization services.

Comment: One commenter asked that post-stabilization care services be limited to services that can be furnished at the facility at which the emergency treatment was provided. Another

commenter recommended that we require M+C organization staff, including plan providers, to defer to an emergency provider's preference to keep an enrollee in an emergency facility after stabilization to prevent any needless disruption in the patient's care.

Response: We disagree that treatment decisions should be limited by what services a facility can provide. If a treating physician or facility is prepared to provide additional needed treatment to a patient, and the M+C organization cannot be reached, or has not responded within an hour, we do not believe that the patient should have to wait for this treatment until the organization responds, simply because it would not be provided in the same physical location as the emergency services. Section 422.113(b)(3) specifies that the physician treating the enrollee must decide when the enrollee may be considered stabilized for transfer or discharge and that decision is binding on the M+C organization. We would expect the M+C organization to allow the treating physician to speak with a plan physician if he or she is concerned about the care (for example, a transfer) planned for the patient.

Comment: One commenter asked which provider, the emergency provider or the M+C plan provider, has the authority to establish a plan of care.

Response: In providing emergency services, the emergency provider has the authority to establish the plan of care. Once the enrollee has been stabilized, post-stabilization care services are provided in accordance with §422.113(c). Thus, once the M+C provider assumes responsibility, then he or she has the authority to revise the plan of care or establish a new plan of care as long as the new plan of care is consistent with a safe transfer of responsibility.

Comment: One commenter recommended that the language in §422.100(b)(iv)(A) be changed from "Pre-approved by the organization" to "Pre-approved by a plan provider or other M+C organization representative."

Response: In response to this comment, we have changed the language in question to read, "Pre-approved by a plan provider or other organization representative." (See §422.113(c)(2)(i).)

3. Service Area Requirements (§§422.2, 422.100, 422.304(b)(2))

In the June 26, 1998 interim final rule, we defined the term "service area" as a geographic area approved by us within which an M+C eligible individual may enroll in a particular M+C plan offered by an M+C organization. We specified that for coordinated care plans and network medical savings account (MSA) plans only, the service area also is the area within which a network of providers exists that meets the access standards in §422.112. Existing regulations also require that an M+C plan's

uniform benefit package must be available throughout a plan's service area (see the discussion below of modifications to this policy made by the BBRA). In deciding whether to approve a service area proposed by an M+C organization for an M+C plan, we consider the M+C organization's commercial service area for the type of plan in question (if applicable), community practices generally, whether the boundaries of the service area are discriminatory in effect, and, in the case of coordinated care and network MSA plans, the adequacy of the provider network in the proposed service area. As discussed in the interim final rule preamble, because of unique rules pertaining to the amount deposited in MSA plan accounts, we may approve single county M+C non-network MSA plans even if the M+C organization has a different commercial service area (63 FR 34971).

We note that since the publication of the interim final rule, we have issued further guidance implementing the definition of service area set forth in §422.2, including an affirmation of our longstanding policy of not approving less than full county service areas unless circumstances justify an exception to this rule. This policy, which we refer to as the "county integrity policy," is explained in detail in OPL 99.090 released April 23, 1999. The county integrity rule, which implements the reference in the service area definition to consideration of whether boundaries are discriminatory in effect, prevents the

establishment of boundaries that could "game" the county-wide M+C payment system by excluding high cost areas of a county. (Note that M+C organizations are paid based on Medicare expenditures at the county level.) Under limited circumstances, as described in OPL 99.090, we will allow an M+C organization to establish a service area that includes a partial county. However, it is never acceptable for an M+C organization to devise an M+C plan service area that excludes portions of a county because it anticipates enrollees with higher health care needs.

Under §422.100(f), an M+C organization may offer more than one M+C plan in the same service area subject to the conditions and limitations for each M+C plan set forth in subpart C of the M+C regulations. For example, §422.100(g) provides that we review and approve each M+C plan to ensure that the service area boundaries do not promote discrimination (for example, that they do not include partial counties unless justified), discourage enrollment, steer specific subsets of Medicare beneficiaries to particular M+C plans, or inhibit access to services.

We received about 20 letters commenting on various aspects of M+C service area policy and an M+C organization's ability to offer multiple M+C plans.

Comment: Several commenters objected to the requirement that each M+C plan offered by an M+C organization must be offered to beneficiaries with a uniform benefit package and cost-sharing

structure that cannot vary throughout each M+C plan's service area. Some of these commenters expressed concern that this requirement will make it difficult for M+C organizations to serve multi-county areas due to the differences in Medicare payment rates across counties, and that this could result in beneficiaries in low-payment or rural counties having decreased access to M+C plans.

Response: As noted by the commenters, existing M+C regulations provide that each M+C plan offered by an M+C organization must be offered to all beneficiaries in an M+C plan's service area with a uniform benefit package and uniform cost-sharing arrangements. This requirement implemented the requirement of section 1854(c) of the Act for uniform premiums for all individuals enrolled in an M+C plan. Thus, under §422.2, an M+C plan was defined as health benefits coverage offered under a policy or contract by an M+C organization that includes a specific set of health benefits offered at a uniform premium and uniform level of cost-sharing to all Medicare beneficiaries residing in the service area of the M+C plan. The BBA requirement that an M+C plan consist of a uniform benefit package that cannot vary in terms of benefits or price throughout the plan's HCFA-approved service area contrasted with our previous "flexible benefits" policy, which permitted HMOs and CMPs under section 1876 to vary premium and benefit offerings by county

within a service area. As discussed in the preamble to the interim final rule, however, an M+C organization was able to achieve the same result as the flexible benefits policy by offering multiple M+C plans, either in the same or in different service areas. This administrative policy allowed an M+C organization great flexibility to offer M+C plans that take into account varying county payment rates and preferences of the Medicare population. (Each M+C plan offered by an M+C organization must have a HCFA-approved service area and meet access standards for health care services as described in our regulations at §422.112.)

As noted in section I.C of this preamble, section 515 of the BBRA amended section 1854 of the Act by adding a new paragraph (h) to permit, effective for contract years beginning on or after January 1, 2001, the application of the uniformity rule to individual “segments” of an M+C plan service area, provided that each segment is composed of one or more M+C payment areas (that is, one or more counties), and a separate complete ACR is submitted for each such segment. The practical implications of this option are similar to our existing administrative policy, under which M+C organizations have the flexibility, by offering multiple plans in a given area or areas, to tailor the benefits offered under their M+C plans to the areas where the plans are offered. In practice, we anticipate that organizations will

likely continue to offer multiple M+C plans, since they have already established such separate plans, and they would have to submit the ACR information required under section 1854(a)(2) of the Act for each segment under the BBRA option, just as they do for each M+C plan now. However, the statute gives M+C organizations the alternative of choosing instead to establish a single M+C plan consisting of segmented service areas, with a separate ACR submission for each segment of the service area. In this final rule, we are adding a new §422.304(b)(2) which reflects section 515 of the BBRA. We also are making needed conforming changes to the definitions of “service area” and "M+C plan" in §422.2, and to §422.100(d) concerning the structure of M+C plans.

Comment: A commenter asked that we clarify our requirements for approving the service area of M+C plans. The commenter stated that the discussion of service area in the preamble and the definition at §422.2 did not provide specific guidance on what constitutes an acceptable service area for an M+C plan offered by an M+C organization.

Response: Although we believe that the service area definition in §422.2 is fairly detailed and specific, we agree that some additional guidance and reorganization of the definition could be of value. Specifically, while our county integrity policy discussed above implements language in the

current definition with regard to discriminatory boundaries, the current regulation text does not expressly reflect our longstanding county integrity policy. In response to this comment, and under our authority in section 1856(b)(1) of the Act to establish M+C standards, we are revising the service area definition to specify that in deciding whether to approve an M+C plan's proposed service area, we consider the following criteria:

(1) Whether the area meets the "county integrity rule" that a service area generally consists of a full county or counties. However, we may approve a service area that includes a portion of a county if we determine that the "partial county" area is necessary, nondiscriminatory, and in the best interests of the beneficiaries.

(2) The extent to which the proposed service area mirrors service areas of existing commercial health care plans or M+C plans offered by the organization.

(3) For M+C coordinated care plans and network M+C MSA plans, whether the contracting provider network meets the access and availability standards set forth in §422.112. Although not all contracting providers must be located within the plan's service area, HCFA must determine that all services covered under the plan are accessible from the service area.

(4) For non-network M+C MSA plans, we may approve single county non-network M+C MSA plans even if the M+C organization's commercial plans have multiple county service areas.

We believe that these revisions to the service area definition, although they do not constitute policy changes, should help to clarify for M+C organizations our method for determining whether a service area is acceptable.

Comment: A commenter supported the M+C standard that the delineation of an M+C plan’s service area should not discriminate against beneficiaries through "gerrymandering" or "red-lining" to deliberately avoid particular areas (for example, to prevent the enrollment of poorer Medicare beneficiaries, or those known to be in poor health). The commenter asked that we also include cultural accommodations (for example, language access) as part of the requirements for service area designation.

Response: We are very concerned that the service areas for M+C plans be drawn in a manner that avoids discriminating against certain groups of beneficiaries who may be perceived as having higher than average health care needs. The general requirement that M+C plan service areas be made up of whole counties, as discussed in OPL 99.090, is intended in part to preclude any incentive to create M+C service areas that serve only the lowest cost population of a particular county. We believe that the revised service area definition, which continues to provide for

our consideration of discriminatory effects, already provides sufficient authority to disapprove a service area if there is evidence that an M+C organization attempted to establish boundaries based upon cultural discrimination, or discrimination against non-English speaking beneficiaries.

Comment: A commenter pointed out that the definition of service area states that the service area also is "the area within which a network of providers exists that meets the access standards in §422.112." The commenter believes that this wording implies that all services must be provided in the service area itself, and that this requirement conflicts with §422.101(a), which states that services obtained outside the geographic area are acceptable if it is common practice to refer patients to sources outside the geographic area. The commenter asked that we allow some services to be furnished outside of an M+C plan's service area if patients traditionally go outside the service area to receive such services. Another commenter stated that the M+C organizations should be permitted the flexibility of structuring plan benefits and provider networks in accordance with local patterns of care regardless of political boundaries. The commenter believes this would afford a broader choice of health care options to beneficiaries.

Response: The intent of the cited language from the service area definition is to require that services are available to a

plan's enrollees through an M+C plan provider network that is accessible from the service area. We have not interpreted this language to prohibit the inclusion in a plan's network of providers physically located outside the area. In fact, as noted above, we allow M+C coordinated care and network MSA plans to establish a provider network with contracting providers located outside of the M+C plan service area, provided that we determine that the M+C organization's contracted provider network meets Medicare access and availability standards at §422.112. We believe that the revised service area definition described above should eliminate any implication that all network providers must be located within the service area.

Under both the former risk contracting program and the M+C program, we generally have required that M+C organizations make health care services available through a network of contracting providers located within the boundaries of the M+C plan service area. Under certain circumstances, however, we have always allowed exceptions to this policy, such as in rural areas when providers were not available in a plan's service area, when traveling outside the service area to obtain health care is not uncommon, and also when the services are still reasonably accessible and available. We have also allowed plans to provide certain specialist services outside of a plan's service area if

the specialist services were not available in the plan's service area and if the specialist was reasonably accessible.

Another reason that we do not require an M+C plan's provider network to be located entirely within the plan's service area is to allow for multiple M+C plans in the same or close geographic areas that share the same provider network, as discussed in the next comment and response. However, we will continue to employ the same criteria in evaluating whether beneficiaries enrolling in an M+C plan are provided with the required access and availability to health care services. Generally, we will evaluate the provider network supporting an M+C plan by considering the prevailing community patterns of care in obtaining health care services (for example, where people obtain care, the types of providers available in the community, reasonable travel times to obtain care) and the access standards at §422.112.

Comment: A commenter notes that an M+C organization can offer multiple M+C plans under a single M+C contract with us. The commenter asks how multiple plans would work, and whether each would be required to have a separate health services delivery system.

Response: In order to respond to the commenter's question, we will briefly review the principal requirements that each M+C plan offered by an M+C organization must independently meet. We

note that these M+C plan requirements also are discussed in greater detail in other parts of this preamble. Each M+C plan must be approved by us through the adjusted community rate (ACR) process, and each M+C plan must be offered to all beneficiaries in the given M+C plan's service area. An M+C organization can offer multiple M+C plans. Each M+C plan offered by an M+C organization must have a HCFA-approved service area that is generally made up of whole counties consistent with our county integrity policy discussed above, and reflected in OPL 99.090. The M+C plans offered by an M+C organization can have the same or different service areas. For example, an M+C organization may choose to offer more than one M+C plan in the same service area in order to provide beneficiaries with a choice of plan benefit packages and cost-sharing structures, including differing basic premium amounts. Also, each M+C coordinated care plan must provide enrolled beneficiaries access to health care service through a network of contracting providers. M+C plans may share the same provider network and portions of the provider network may be located outside of the plan's service area. However, the provider network supporting an M+C plan must meet M+C access standards with respect to all enrollees in that plan's service area (see §422.112) as determined by HCFA. We note that under §422.501(e), when an M+C organization includes several M+C plans under a single contract, the contract must provide for an

amendment upon our request to remove an individual M+C plan from the contract, so that we have the flexibility to nonrenew or terminate only a single M+C plan if a problem is confined to one such plan.

4. Benefits (§§422.2, 422.100, 422.101, 422.106)

The regulations contained in subpart C describe the requirements for M+C organizations' benefit offerings. The statutory basis for these provisions generally can be found in section 1852 of the Act. The basic categories of benefits parallel those that applied under the section 1876 risk contracting program with the exception of the use of the term "basic benefits," which we now define as both original Medicare benefits and additional benefits. Despite the limited changes, we believe it is important to carefully define the different benefit categories, because, historically, organizations participating in the risk-contracting program often used different terminology in describing their benefit packages to beneficiaries and in structuring benefits under Medicare risk contracts.

Thus, in order to promote consistency, M+C organizations must use the benefit terminology specified in the M+C regulations and in instructions and operational policy letters. We intend to provide further instructions over the next several years to assist organizations in standardizing the structure and

terminology used in describing their benefit offerings. In addition to issuing instructions, we will be reviewing benefit design closely to provide feedback to M+C organizations on ways they can improve their benefit descriptions and ensure that the benefits comply with our requirements. The use of consistent terminology in describing benefit categories will result in better information for Medicare beneficiaries to compare their Medicare options as well as help us to review both benefits paid for with Medicare capitation payments and benefits for which Medicare beneficiaries are charged a premium.

Comment: Several commenters asked for additional clarification regarding the new definitions of the benefit categories under the M+C program.

Response: We have been aware of confusion about the benefit terminology used in the Medicare risk contracting program, and have attempted to clarify the terminology in the M+C regulations. As noted above, a significant change under the M+C program involves the definition of the term "basic benefits." Under the M+C program, basic benefits means both benefits covered under original Medicare and additional benefits, not otherwise covered under original Medicare, that are paid for with Medicare payments. Additional benefits are grouped with original Medicare benefits because they are part of the package of basic benefits for which beneficiaries are not charged a premium, beyond any

premium the M+C organization is permitted to charge for original Medicare benefits. As discussed more fully below in section II. D, the costs of additional benefits are funded by the difference between an organization's ACR for the original Medicare benefit package, and the M+C payment plus any approved enrollee cost sharing.

Mandatory supplemental benefits are M+C plan benefits not otherwise covered under original Medicare for which anyone who enrolls in an M+C plan is charged a premium. Thus, additional benefits (included in the basic benefit package) and mandatory supplemental benefits are similar in that they are not covered by original Medicare, and all M+C enrollees receive them as part of their M+C plan. The difference is in the way these benefits are funded: additional benefits are funded with Medicare payments through the M+C payment rate, and mandatory supplemental benefits are fully paid for by M+C enrollees through a separate premium or cost sharing.

Like additional benefits and mandatory supplemental benefits, optional supplemental benefits are not covered by original Medicare. However, plan enrollees may choose whether to elect and pay for optional supplemental benefits. M+C organizations may offer M+C plans that have individual items or groups of items and services as optional supplemental benefits.

We are making several minor technical changes to improve the accuracy and consistency of the benefit-related definitions set forth in §422.2. For example, we are clarifying under the definitions of "mandatory supplemental benefits" and "optional supplemental benefits" that these categories of benefits consist of "health care services" that may be paid through premiums "and/or" cost sharing. Also, we are clarifying in the definition of "benefits" that the costs an M+C organization incurs in providing benefits may not be solely an administrative processing cost and that benefits must be "submitted and approved through the ACR process."

Comment: Commenters suggested that we consider developing standardized definitions or descriptions for the individual items and services that make up a benefit package.

Response: The intent of the regulations is to clarify the meaning of the terms used in the statute, which reflect the funding source for various groups of benefits. We recognize the value of standardizing the definitions of individual items and services that might be included as additional or supplemental benefits, such as a drug benefit. Both the annual Summary of Benefits and the Plan Benefit Package are important parts of our standardization efforts. As noted above, we intend to provide further instructions over the next several years to assist organizations in standardizing the terminology used in describing

their benefit offerings. Work on defining individual items and services so that beneficiaries may compare benefit offerings is taking place predominantly within the context of our information campaign. We are not including standardized definitions in this final rule.

Comment: Several commenters asked for further clarification of the meaning of the requirement in §422.101(a) that an M+C organization provide all Medicare-covered services that are available to beneficiaries residing in a plan's geographic area, including services obtained outside of the area if it is common practice to refer patients to sources outside the area. Two commenters noted that the term "common practice" might be misleading, and recommended that we revise the regulations to state that services may need to be provided outside the area, provided that the services are reasonably accessible to enrollees and such use is consistent with community practice patterns. One commenter recommended that we confirm in the final rule the basic premise that M+C organizations must provide all their enrollees with all services covered under original Medicare, including any needed out-of-area care. Another commenter questioned whether the requirement that an M+C organization provide all Medicare-covered services that are available to beneficiaries residing in the service area implies that the M+C organization’s health care

delivery patterns must mirror care delivery patterns in original Medicare.

Response: Consistent with section 1852(a)(1)(A) of the Act, §422.101(a) establishes the principle that an M+C organization must provide its plan enrollees with all the Medicare-covered services available to other Medicare beneficiaries in the area served by the plan. We recognize that the existing regulatory language in this section creates some potential for confusion and are making several changes along the lines suggested by commenters in order to clarify the regulations. Revised §422.101(a) continues to specify that an M+C organization must provide coverage of all Medicare-covered services available to beneficiaries residing in a plan's service area. We are adding a provision to state explicitly that services may be provided outside of the service area of the plan if the services "are accessible and available to enrollees in the same area."

When we assess the capability of any proposed plan to serve an M+C service area, we consider the numbers, types, and locations of all providers needed to provide all Medicare-covered services or, in regulation terms, the access and availability of Medicare-covered services. We continue to believe that it is in the best interest of the Medicare program and Medicare beneficiaries to evaluate proposed M+C plan networks on a case-by-case basis taking into account the patterns of care and access

to care in particular geographic areas. It is not unusual for services such as a dialysis center or transplant center not to be available in a county. If, for example, a Medicare beneficiary would normally have to travel to a different county for renal dialysis or a transplant, we believe it would not be unreasonable for an M+C plan enrollee to be required similarly to travel outside of a service area for access to such services. Such exceptions to in-area care access should, however, be limited in order to have a viable M+C plan.

The fundamental requirement under §422.101(a) that an M+C organization provide coverage for all Medicare-covered services is not intended to dictate care delivery approaches for a particular service. For example, M+C organizations may furnish a given service using a defined network of providers, some of whom may not see patients in original Medicare. M+C organizations may also encourage patients to see more cost-effective provider types than would be the typical pattern in original Medicare (as long as those providers are working within the scope of care they are licensed to provide, and the M+C organization complies with the provider antidiscrimination rules now set forth under new §422.205).

M+C organizations' flexibility to deliver care using cost-effective approaches should not be construed to mean that Medicare coverage policies do not apply to the M+C program. If

original Medicare covers a service only when certain conditions are met, these conditions must be met in order for the service to be considered part of the Medicare benefits component of an M+C plan. M+C plans may cover the same service when the conditions are not met, but these benefits would then be defined as additional or supplemental.

In summary, each M+C plan must include all Medicare-covered services available in the service area served by the M+C plan, with the exception of hospice services. Our longstanding policy of allowing organizations flexibility in the provision of services (for example, in terms of who provides the service, what equipment is used, where the service is provided, and what procedure is used) has not been affected by the BBA. Organizations are required to provide services within the guidelines of Medicare national coverage policy and other Medicare rules and requirements that apply to the traditional Medicare fee-for-service system. When a health care service can be Medicare-covered and delivered in more than one way, or by more than one type of practitioner, we continue to recognize a managed care organization's right to choose how services will be provided. These decisions have been left to managed care organizations to allow them to maximize their value purchasing power, and use resulting savings to provide services not covered by the Medicare program.

Comment: Several commenters raised questions about the requirements in §422.101(b) that M+C organizations comply with our national coverage decisions and with the coverage decisions of local carriers and intermediaries with jurisdiction for claims in an M+C plan's geographic area. Among the issues raised were the following.

• The national requirements which must be followed, and the meaning of "HCFA's national coverage decisions".

• General confusion about the relationship between national coverage decisions and local medical review policy.

• Need for additional guidance in situations when plan service areas extend over a geographic area involving multiple carriers or intermediaries, and thus potentially conflicting medical review policies.

• Difficulties in obtaining coverage decisions by local carriers and intermediaries, and the unwillingness of some carriers to permit M+C organizations to be represented on carrier advisory boards.

Response: As discussed in detail above, M+C organizations must provide their plan enrollees access to all Medicare covered services. However, there is a distinction between the general rule that a health care service is covered under Medicare and the decision that an individual patient fits the clinical criteria necessary for receipt of the service. National coverage

determinations and local medical review policies establish what could be a covered benefit under Medicare and the clinical criteria under which the benefit must be provided. The M+C organization must determine whether or not an individual patient fits this clinical criteria. This process at the plan level constitutes an organization determination. In making organization determinations, M+C organizations are required to follow all national coverage determinations and relevant local medical review policies.

It is important to note, that all M+C organization determinations must be made based on the individual circumstances of a given case, using the best and most relevant information available. All organization determinations are subject to enrollee appeals to the M+C organization and subsequently to an independent review entity. The fact that an M+C organization determination was applying a local medical review policy does not in itself ensure that an appeal to the independent review entity might not result in a determination that the service in question was medically necessary for the individual enrollee and therefore should be covered.

In this final rule, we are revising §422.101(b)(1) to clarify that the requirement that M+C organizations comply with national coverage decisions includes following the general coverage guidelines included in original Medicare’s manuals and

instructions to contractors, unless superseded by the M+C regulations or operational policy letters. The Coverage Issues Manual is the primary resource for national coverage decisions. Additional guidance on coverage of hospital and skilled nursing services, home health services, physician services, and other Medicare services can be found in the instructions in the Carriers, Intermediaries, and other HCFA manuals. In the absence of a national standard, M+C organizations should follow local medical review policies in making medical necessity decisions.

We recognize the potential for conflicting local medical review policies when an M+C plan's service area extends across the jurisdictions of more than one carrier, for example. Our general rule under OPL 46 continues to be that the M+C organization should apply the medical review policy of the Medicare carrier in the area where the services are furnished, since that is the policy that would apply to those services under original Medicare. However, as one commenter pointed out, an M+C organization is not precluded from covering services that a local carrier may have determined are not covered, if the organization's own utilization and quality management standards support the medical necessity of the service. Similarly, an organization may occasionally need to make a coverage determination in a situation when there is neither national coverage policy or relevant local review guidelines. In all such

cases, an M+C organization's fundamental responsibility is to use the best information available to make an informed decision on the medical necessity of a given service, and then to provide the medically necessary service, even if doing so may conflict with local medical review policies.

One way for an M+C organization to attempt to pursue consistency in medical review policies is to participate on the review boards of local carriers or intermediaries. We are aware of the difficulties M+C organizations are encountering in some areas of the country in participating on these boards, and are actively working to address this issue. We remain committed to establishing more standardized procedures for developing medical review policies, and for increasing M+C representation in formulating these policies.

Comment: Several commenters requested clarification of our policy regarding employer groups and the coordination of benefits with employer group health plans (EGHPs). They asked for clarification as to whether members of an EGHP had to be offered the same benefits as other Medicare enrollees, and whether it would be acceptable to offer an actuarial equivalent package. Another commenter asked that §422.106 be amended to address coordination of Medicaid benefits, as well as EGHP benefits.

Response: EGHPs that are offered by an M+C organization must provide Medicare-eligible EGHP members the same benefits

provided to all other Medicare enrollees under the M+C plan in which the beneficiary is enrolled. The benefits in the M+C plan may not be reduced or otherwise changed, and actuarially equivalent benefits may not be substituted in place of the M+C plan benefits. As noted below in the next response, EGHP benefits beyond those benefits offered under the M+C plan are considered outside the purview of our regulatory authority under the M+C program. However, we retain the authority and responsibility to assure that all Medicare beneficiaries enrolled in organizations that have a contract with Medicare (even if they are dually entitled to coverage under another plan) receive the same benefits and protections as other Medicare beneficiaries enrolled in the plan.

We recognize that the existing regulations describing these situations are somewhat unclear. Therefore, we are revising the language at §422.106 by reorganizing its requirements for clarity. Revised §422.106(a)(1) clarifies that if an M+C organization contracts with an EGHP that covers enrollees in an M+C plan, or contracts with a State Medicaid agency to provide Medicaid benefits to individuals who are eligible for both Medicare and Medicaid, and who are enrolled in an M+C plan, the enrollees must be provided the same benefits as all other enrollees in the M+C plan, with the EGHP or Medicaid benefits supplementing the M+C plan benefits. Section 422.106(a)(1)

states that all M+C program requirements apply to the M+C plan coverage provided to enrollees eligible for benefits under an EGHP or Medicaid contract. We also are revising §422.106 to delineate clearly that our review authority extends only to the M+C plan benefits provided to members of the EGHP, and the associated marketing materials, rather than to any other complementary benefits provided only under the EGHP. The rules contained in this regulation and the corresponding instructions and operational policy letters take precedence for benefits included in the M+C plan.

We are also adopting the commenter's suggestion that §422.106 incorporate our requirements concerning the coordination of M+C and Medicaid benefits. These rules are conceptually identical to those governing EGHPs. Thus, for individuals dually eligible under Medicare and Medicaid who are enrolled in an M+C plan, the enrollees must be provided the same benefits as all other enrollees in the M+C plan, with the Medicaid benefits supplementing the M+C plan benefits.

Comment: One commenter questioned whether group health benefits offered by employers were considered to be supplemental benefits under the M+C program.

Response: Employer group health plan benefits paid by an employer on behalf of an employee or retiree, as well as Medicaid benefits furnished under a Medicaid State plan, are neither basic

nor supplemental benefits. They are therefore outside the scope of M+C plan benefits regulated by the Medicare program. Other laws and regulations may apply to these benefits (such as ERISA requirements for EGHPs). We recognize in §422.106 that M+C organizations may contract with employers to furnish benefits that complement those that an employee or retiree receives under an M+C plan. Such benefits may include M+C plan premiums, cost sharing, and additional services. M+C organizations may design an M+C plan with the expectation that an employer group will offer a particular set of complementary benefits. In such a case, however, the M+C plan must be offered to all Medicare beneficiaries in the service area, regardless of whether they are eligible for the employer group benefits, and meet all other M+C plan requirements.

Comment: Several commenters expressed confusion regarding the benefit-related implications of the "conscience protection" provision contained in section 1852(j)(3) of the Act, which is a new provision giving enrollees rights to unrestricted physician counseling and advice. Under the conscience protection provision in section 1852(j)(3)(B) of the Act, implemented in §422.206(b), the prohibition on interference with provider advice to enrollees in section 1852(j)(3)(A) of the Act (reflected in §422.206(a)) may not be construed to require an M+C organization to provide or pay for counseling or referrals if the organization objects on

moral or religious grounds and notifies enrollees of its policies in this regard. Some commenters asked whether the conscience clause in section 1852(j)(3)(B) of the Act and §422.206(b) would permit an M+C organization to refuse to include a Medicare-covered service in its M+C plan, as otherwise required under §422.101.

Response: The conscience protection in section 1852(j)(3)(B) of the Act affects only obligations under section 1852(j)(3)(A) of the Act, not obligations that arise elsewhere in the statute, such as the obligation under section 1852(a)(1) of the Act to cover all Medicare-covered services available in the area served by the M+C plan. To the extent the operation of the right to advice and counseling under section 1852(j)(3)(A) of the Act would obligate an M+C organization to cover counseling or referral services that it would not otherwise be obligated to cover, section 1852(j)(3)(B) of the Act allows the organization to decline to provide such service on conscience grounds if appropriate notice is provided to beneficiaries. However, if the service is one that the organization is obligated to provide independent of section 1852(j)(3)(A) of the Act, it could not be affected by a provision that by its own terms affects only the way that "[s]ubparagraph (A) [of section 1852(j)(3)] shall. . . be construed." It in no way affects obligations that arise elsewhere in the statute. Therefore, an M+C organization could

not rely upon section 1852(j)(3)(B) of the Act or §422.206(b) in an attempt to avoid coverage of services that it is obligated under section 1852(a)(1) to cover.

We note, however, that in the case of abortion-related services, Congress has provided M+C organizations with conscience protections independent of that in section 1852(j)(3)(B) of the Act. Specifically, under section 211 of the fiscal year 2000 Department of Health and Human Services Appropriations Act, Pub. L. 106-113, we are prohibited from denying a M+C contract to an entity on the grounds that it refuses on conscience grounds to cover abortions. We are required, however, to make appropriate adjustments to such an entity’s M+C capitation payments to cover our costs in providing Medicare-covered abortion services outside the M+C contract.

Comment: Commenters requested that copayments for outpatient psychiatric services be limited to the same percentages of copayments allowed for other services.

Response: With the sole exception of out-of-area emergency services, we have not prescribed limitations on copayments for individual Medicare services in the M+C regulations. In this case, the commenter's suggestion would impose a requirement on M+C organizations that is inconsistent with the cost-sharing structure of original Medicare. We do not believe this would be appropriate.

5. Special Rules for Screening Mammography, Influenza Vaccine, and Pneumococcal Vaccine (§422.100(h))

Section 422.100(h) establishes special rules for screening mammography, influenza vaccine, and pneumococcal vaccine. Enrollees of M+C organizations may directly access, through self-referral, screening mammography and influenza vaccine. In addition, M+C organizations may not impose cost sharing for influenza vaccine and pneumococcal vaccine.

Comment: Several commenters expressed concern that enrollees may directly access out-of-network providers through self-referral. They believe that self-referrals should be limited to in-network providers. Furthermore, they feared that an enrollee may self-refer to noncertified facilities or noncredentialed providers.

Response: The right to directly access screening mammography services and flu vaccines does not include accessing these services out of network. Section 422.112(a) specifies that an M+C organization "may specify the networks of providers from whom enrollees may obtain services" if the organization meets a number of specified conditions. M+C organizations thus have the discretion under §422.100(h)(1) to require that self-referrals be made to a provider within the M+C plan’s network, as long as sufficient access is provided in that network. We note that if an M+C organization offers a point-of-service (POS) option under

its M+C plan, an enrollee selecting this option could self-refer to an out-of-network provider, consistent with the payment rules established by the M+C organization.

Comment: One commenter stated that we should prohibit cost sharing for mammography as well as vaccines, noting that both health care services are preventive in nature and would be cost-effective measures for the Medicare program in the long term. The commenter pointed out that women constitute a substantial portion of the Medicare population, and asserted that allowing cost sharing for screening mammographies could be perceived as both gender-specific and discriminatory in nature.

Response: Various provisions of Title XVIII of the Social Security Act specify the coverage of mammography, influenza vaccine, and pneumococcal vaccine. The Act provides that there should be no deductible for any of these services. Further, while the Act indicates that there be no copayment for influenza and pneumococcal vaccine, it provides for a 20 percent coinsurance for mammography. (See, for example, section 1834(c) of Title XVIII and 42 CFR §410.152(h).) These are policies established by statute for the original Medicare program, and we see no basis for requiring M+C organizations to provide more favorable treatment to M+C enrollees than that provided to original Medicare beneficiaries.

Comment: A commenter requested that we clarify in the regulations that the prohibition on cost-sharing for influenza and pneumococcal vaccine applies to the imposition of cost-sharing on M+C plan enrollees.

Response: As requested by the commenter, we have added language to the regulation text to clarify that M+C organizations are prohibited from imposing cost sharing "on their M+C plan enrollees" for influenza and pneumococcal vaccines.

6. Special Rules for Point-of-Service (POS) Option (§422.105)

A POS benefit is an option that an M+C organization may offer under an M+C coordinated care plan, or network M+C MSA plan, to provide enrollees in such plans with additional choice in obtaining specified health care services. A coordinated care plan may include a POS option as an additional benefit, a mandatory supplemental benefit, or an optional supplemental benefit. A network MSA plan may include a POS option only as a supplemental benefit.

Under a POS option, the M+C organization generally permits enrollees to obtain specified items and services outside of the M+C plan’s normal prior authorization rules, but provides that enrollees will incur higher financial liability for such services. The enrollee may be required to pay a premium for the benefit unless the benefit is offered as an additional benefit. M+C organizations can establish what services are available under

a POS benefit and the amount of member cost sharing subject to ACR limits. M+C organizations may also place other limits on the benefit; for example, a plan could offer a POS benefit as a travel benefit allowing members to access specified services when the member is traveling outside of the plan's service area.

Comment: Several commenters objected to the restriction in the interim final regulation at §422.105(a) stating that a POS benefit can be used only to obtain services from providers that do not have a contract with the M+C organization. The commenters maintained that an important aspect of a POS benefit is that it allows beneficiaries who have reservations about joining a managed care plan the opportunity to enroll without following strict prior authorization requirements to access services, and that this consideration applies without regard to whether the provider is part of the M+C plan network. Some commenters also noted that the restriction against in-network use of a POS benefit was particularly unfair to M+C plans with large provider networks, since the likelihood of an in-network referral was much greater. Several commenters stated that if we are concerned about in-plan use of a POS benefit, the solution is monitoring rather than prohibiting beneficiary choice.

Response: In the interim final M+C regulations, we specified that an M+C POS benefit could be used by plan members only to obtain health care services from providers outside of the

plan's contracted provider network (non-network providers). The intent of this restriction was to ensure that plan enrollees were not inappropriately induced to use a POS benefit to obtain services at higher cost from plan contracting providers that they could otherwise receive at lower cost by following the plan authorization rules for obtaining health care services. However, we have reconsidered this position in response to the above comments, and in recognition of the fact that a number of organizations withdrew their POS benefit due to this restriction. We recognize that for some beneficiaries the ability to obtain health care services directly from providers without obtaining advance authorization is an important choice. Accordingly, in order to ensure that beneficiaries have the widest possible array of choices, we have decided to allow plans the option of offering a POS benefit that can be used by plan members to receive services from plan contracting providers.

We remain concerned about the potential for inappropriate cost-shifting to beneficiaries. To help guard against this possibility, we have revised §422.105 to require that M+C organizations offering a POS benefit must track, and report to us upon request, POS utilization at the M+C plan level by both contracting providers and noncontracting providers. In monitoring use of the POS benefit, we will pay particular attention to potential over-utilization of the POS benefit by

plan enrollees in obtaining services from the plan contracting provider network. We will attempt to verify that it is a matter of choice when a plan member uses a POS benefit to obtain services, rather than due to the member being inappropriately denied prompt access to the service by the plan. We note that an M+C organization still has the option of offering a POS benefit through an M+C plan that can be used by plan members only to obtain health care services from providers who do not contract with the plan.

Comment: A commenter asked if the POS regulations apply to POS benefits that are offered only for employer group members. The commenter noted that under §422.106, employer group benefits that are designed to complement the Medicare benefits are exempted from our review.

Response: An employer may through negotiation with an M+C organization provide a POS benefit for members of an employer group who elect to join an M+C plan. As described in the regulations at §422.106, such enhancements to the Medicare-approved benefit package are not subject to our review or approval.

Comment: A commenter expressed concern about the requirement at §422.105(d)(2)(iv) that a POS benefit must have a maximum annual out-of-pocket cap on enrollee liability. The commenter questioned whether capping enrollee out-of-pocket

expenses would leave the plan at risk for all out-of-network care received by the enrollee once the cap was exceeded.

Response: As the commenter stated, M+C plans offering a POS benefit must place an annual maximum cap on an enrollee's financial liability in using a POS benefit. The reason for requiring a cap on beneficiary financial liability is to ensure that beneficiaries understand in advance what their maximum financial risk is in using a POS benefit. However, once the annual maximum for a POS benefit is reached (including the beneficiary cap), the plan does not have to continue paying for health care service under a POS benefit. For example, consider a plan that offers a POS benefit with a $5,000 annual maximum, and requires 20 percent coinsurance from the beneficiary using the POS benefit. In this example, the member's annual maximum financial liability under POS is $1,000 (20 percent of $5,000). Once the $5,000 overall POS annual maximum is reached, the beneficiary has paid the out-of-pocket maximum of $1,000 and the plan has contributed $4,000 of the $5,000 annual maximum for the POS benefit. At this point, the plan has no further obligation to cover services for the beneficiary under the POS benefit. Thus, any use of the POS benefit beyond this maximum would be at the enrollee's financial liability. We note that §422.105(d)(2)(iii) specifies that an M+C organization must explain in the Evidence of Coverage the enrollee's financial

responsibility for services that are not covered under the POS benefit or services beyond the maximum POS limit.

In general, we expect that organizations offering a POS benefit will be able to provide enrollees with timely information on the POS financial limits, coverage rules, and enrollee cost-sharing for a given service, including the capacity to provide enrollees with advance coverage information over the phone. For example, if the POS benefit has an annual dollar cap, enrollees should be able to phone the organization offering the POS benefit and be informed of how close they are to reaching the financial cap on the benefit. In addition, the plan should be able to advise an enrollee whether a particular service will be paid for under a POS benefit, how much the member will pay out-of-pocket, and how much the plan will contribute under the POS benefit.

7. Medicare Secondary Payer (MSP) Procedures (§422.108)

As stated in the June 26, 1998 interim final rule, Medicare does not pay for services to the extent that there is a third party that is to be the primary payer under the provisions in section 1862(b) of the Act and 42 CFR Part 411. The M+C organization must, for each M+C plan, identify payers that are primary to Medicare under section 1862(b) of the Act and part 411; determine the amounts payable by those payers; and

coordinate its benefits to Medicare enrollees with the benefits of the primary payers.

The M+C organization may charge, or authorize a provider to charge, other individuals or entities for covered Medicare services for which Medicare is not the primary payer. If an enrollee receives from an M+C organization covered services that are also covered under State or Federal workers' compensation, any no-fault insurance, or any liability insurance policy or plan, including a self-insured plan, the M+C organization may charge, or authorize a provider to charge the insurance carrier, the employer, or any other entity that is liable for payment for the services under section 1862(b) of the Act and part 411 of this chapter, or the M+C enrollee, to the extent that he or she has been paid by the carrier, employer, or entity for covered medical expenses.

Where Medicare is a secondary payer to employer coverage in the case of certain working Medicare beneficiaries, an M+C organization may charge a group health plan (GHP) or large group health plan (LGHP) for services it furnishes to a Medicare enrollee who is also covered under the GHP/LGHP, and may charge the Medicare enrollee to the extent that he or she has been paid by the GHP/LGHP.

Comment: Two commenters requested that the M+C regulations provide that Medicare secondary payer regulations apply generally

to M+C organizations. One of these commenters also favored a cross reference to the Medicare overpayment regulations.

Response: M+C organizations are to apply only the Medicare secondary payer (MSP) rules as found in section 1852(a)(4) of the Act and in §422.108. Other MSP provisions do not apply to M+C organizations, and they do not have recourse to them. However, M+C organizations are expected, as provided under §422.108(a), to look to section 1862(b) of the Act and 42 CFR Part 411 to determine whether Medicare or some other party is the primary payer.

Since section 1852(a)(4) of the Act and §422.108 are the only MSP provisions that apply in the M+C context, M+C organizations would pursue their Federally authorized claims under State law. Federal preemption of State laws in the MSP context would occur only to the extent a State law would prohibit an M+C organization from complying with what the Federal rules authorize (that is, from billing and recovering from specified third parties, and from beneficiaries to the extent they have received third party payments that are primary to Medicare under MSP rules). These recoveries are not made on behalf of the United States and, therefore, the Federal overpayment rules cited by the commenter do not apply.

Comment: One commenter requested that enrollees be given written notice of their right to appeal an M+C organization

decision to withhold payment under MSP rules, or file a request for a waiver of recovery of the overpayment.

Response: Section 422.568 requires an M+C organization to give an enrollee written notice of any denial, in whole or in part, which includes a description of the enrollee's appeal rights. It is not necessary to create a separate requirement in the MSP context. With respect to a request for waiver of recovery of the overpayment, since any recoveries are not obtained on behalf of the United States, State laws rather than Federal overpayment rules would apply.

Comment: One commenter believes that if an M+C plan enrollee with coverage primary to Medicare obtained services from providers not participating in the M+C plan, the M+C organization should pay for the services. By paying nonplan providers first, and then seeking recovery from the primary payer, the beneficiary would not be held responsible for the bill.

Response: There is no statutory authority to require M+C organizations to make payments to nonplan providers, except in the circumstances set forth in §422.100(b)(1) (for example, emergency or urgently needed services, out-of-area dialysis) and §422.114(b) (for example, access to services under an M+C private fee-for-service plan).

Comment: Three commenters recommended that since some States have laws that do not allow HMOs and health insurers to

seek payment from primary payers, the regulations should be clarified to indicate that MSP rules preempt any State laws that would prevent an M+C organization from complying with the Federal law and regulations.

Response: We are adding a new paragraph "f" to §422.108 to clarify that a State cannot take away an M+C organization's Federal rights to bill or authorize providers to bill for services for which Medicare is not the primary payer. However, nothing in section 1852(a)(4) of the Act would prohibit a State from limiting the amount of the recovery; therefore, State law could modify an M+C organization's rights in this regard, but could not deny them entirely.

Comment: One commenter believes that the use of the term "charge" in this section is not appropriate. The commenter pointed out that "charge" has a specific meaning in the Medicare context (as in "reasonable charge"), and the use of "charge" in this section is not consistent with the commenter's understanding of the common meaning of this term. The commenter recommended revising the regulations to use the term "bill" or "collect from." The same commenter also suggested that there was ambiguity in the use of the word "determine" in §422.108(b)(2), because "determine" and "determinations" also have different specific meanings under Medicare. "Calculate" or "identify" was suggested as a replacement.

Response: The intended meaning of "charge" as used in this section is "the imposing of a pecuniary obligation on another entity." Although this usage is technically correct and consistent with statutory language, in the interest of clarity, we are adopting the commenter's request, and changing "charge" to "collect from" in the regulation headings, and to "bill" in the body of the regulation text. We also have changed "determining" to "identify" in subsection (b)(2).

8. National Coverage Determinations (§422.109)

Section 422.109 addresses how M+C organizations are paid when a new Medicare benefit is required under a national coverage determination, but payment for this benefit is not yet included in the organization's capitation rate. Frequently, we develop coverage policy on new procedures or technology during the year. M+C organizations must provide these benefits as soon as they are covered by Medicare, even if this occurs during the middle of a contract year. If the cost of such new benefits exceeds a specified threshold, we pay the M+C organization on a fee-for-service basis under original Medicare payment rules to cover the services in question.

Comment: Commenters requested that we include a definition of "national coverage determination" in the M+C regulations, and objected to the fact that beneficiaries would be liable for paying the Part A deductible, when the beneficiary in most cases

has already been charged premium or cost-sharing amounts based on the actuarial value of this deductible.

Response: The definition of "national coverage determination" was not included in the M+C regulations because it is already set forth in §400.202 of title 42 of the CFR; however, for the convenience of users of the M+C regulations, we have now repeated this definition in §422.2. With respect to the issue of the Part A deductible, section 1852(a)(5)(A) of the Act provides that services covered by a national coverage determination involving significant costs not included in M+C capitation payments are not covered as a service that must be provided under the M+C contract in exchange for capitation payments. Section 1852(a)(5)(B) of the Act provides that the normal rule that capitation payments are made in lieu of regular Medicare payments (section 1851(i)(1) of the Act) does not apply in the case of additional services covered under a national coverage determination. Thus, the services would be covered under original Medicare's coverage rules. Congress did not provide for a similar exception, however, to the rule in section 1851(i)(2) of the Act providing that "only the M+C organization shall be entitled to receive payments from the Secretary under this title for services furnished to [an M+C enrollee of that organization]." Read together, these provisions mean that the M+C organization will receive Medicare payment under original

Medicare's payment rules for services covered by a national coverage determination that triggers the procedures in §422.109.

Under these payment rules, a beneficiary is liable for deductible and cost-sharing amounts, which is why §422.109(b)(5) provides that enrollees would pay these amounts. Although the enrollee has in most cases paid a premium and other cost sharing based on the actuarial value of Part A and Part B deductibles and cost sharing, this amount is for services covered under the contract. These services are covered outside the contract under original Medicare payment rules. However, since the general Part A deductible arguably would already have been satisfied for the beneficiary through M+C plan premiums and cost sharing, we are revising §422.109(b)(5) in response to this comment to provide that M+C enrollees are responsible only for coinsurance amounts. Medicare payments will thus be made without regard to satisfaction of the Part A deductible.

9. Discrimination Against Beneficiaries Prohibited (§422.110)

Consistent with section 1852(b)(1) of the Act, §422.110 establishes that an M+C organization may not discriminate among Medicare beneficiaries based on any factor that is related to health status, including, but not limited to the following factors: medical condition (including mental as well as physical illness), claims experience, receipt of health care, medical history, genetic information, evidence of insurability (including

conditions arising out of acts of domestic violence), or disability. The only exception to this rule is that an M+C organization may not enroll an individual who has been medically determined to have end-stage renal disease (unless the individual is already enrolled with the organization under a different plan). M+C organizations are required to observe the provisions of the Civil Rights Act, Age Discrimination Act, Rehabilitation Act of 1973, and Americans with Disabilities Act.

Comment: One commenter suggested that we require M+C organizations to provide handicapped-accessible facilities for marketing presentations, full access to plan information and plan providers, as well as access to the M+C organization itself.

Response: This comment speaks to the practice of health screening and the allocation of marketing resources with respect to disabled populations. Section 422.110(c) requires M+C organizations to meet the requirements of the Americans with Disabilities Act (ADA). Consistent with ADA, an M+C organization must ensure that its providers and marketing presentations accommodate persons with disabilities, both in terms of physical accessibility and communication of information. Thus, the organization and providers must afford the same freedom of choice with respect to providers to all enrollees. Further, access to information must be provided in appropriate alternative formats upon request, such as Braille, enlarged font (at least 14 point),

audio cassette, closed or open captioning, or formats that accommodate low-literacy beneficiaries. In providing information access to hearing-impaired individuals, M+C organizations must not rely on relay services but must make available TTY/TDD service as well. Again, these requirements are consistent both with the Americans with Disabilities Act and with the M+C provisions in §422.80(e)(2) regarding marketing to the disabled population.

10. Disclosure Requirements (§422.111)

Section 1852(c) of the Act lists several areas where an M+C organization must disclose specific information to each M+C plan enrollee. These disclosure requirements are set forth in §422.111 of the regulation. M+C organizations are required to provide to each M+C plan enrollee, at the time of enrollment and at least annually thereafter, in a clear, accurate, and standardized form (that is, through the Evidence of Coverage), the following information regarding the enrollee's M+C plan: service area, benefits offered under the plan and under original Medicare, access to providers, out-of-area coverage, emergency coverage, supplemental benefits, prior authorization rules, grievance and appeals rights and procedures, quality assurance programs, and disenrollment rights and responsibilities.

M+C organizations are also required to provide additional information upon request of a beneficiary, including: general

coverage and comparative plan information, information on the number and disposition of grievances and appeals, information on the financial condition of the M+C organization, the procedures the organization uses to control utilization of services and expenditures, and a summary of physician compensation arrangements. Section 422.111 also includes procedures for an M+C organization to follow when it intends to change its rules for an M+C plan, and describes the enrollee notification requirements when there are changes in a plan's provider network.

Finally, as discussed in section II.B of this preamble, §422.64 no longer lists the information that we must provide to beneficiaries. However, because §422.111 referred to this material in several places, we are revising §422.111 to incorporate the necessary specifications into a new paragraph (f).

Comment: Several commenters acknowledged the importance of providing beneficiaries with information on their range of health care choices, so that they can make informed decisions about their Medicare coverage. However, they were concerned that duplication of efforts will result from our responsibilities to provide beneficiaries with the information formerly specified in §422.64(c) (now set forth in §422.111(f)) combined with the requirements in §422.111 concerning information that an M+C organization must disclose to its enrollees. The commenters

viewed these requirements as an unnecessary overlap of information.

Response: We have no intention of burdening M+C organizations with unnecessary disclosure requirements that duplicate our efforts. However, just as section 1851(d) of the Act mandates our responsibilities for distributing information to all beneficiaries (including the requirement at section 1851(d)(7) of the Act that M+C organizations provide us with the information needed to carry out these responsibilities), section 1852(c) of the Act establishes several specific requirements for M+C organizations to disclose plan information to their enrollees, and to individuals eligible to enroll in their plans. The M+C regulations do not expand upon the disclosure requirements set forth in the M+C statute. In general, the plan-specific information that we collect from M+C organizations for Medicare Compare (our database of comparative plan information) can also be used by M+C organizations to meet their statutory information disclosure responsibilities. Thus, although the statute does mandate that M+C organizations report similar information both to us and to their plan enrollees, we do not believe that the M+C disclosure requirements should result in significant additional burdens for M+C organizations.

Comment: Commenters discussed the importance of conveying required information to beneficiaries in a culturally competent

manner. They suggested that criteria be developed by us for use by M+C organizations.

Response: We agree that plan information needs to be provided to beneficiaries in a culturally competent manner, so that beneficiaries are provided with the opportunity to make fully informed health care choices. We note that §422.80(c)(5) addresses this concern by specifying that, for markets with a significant non-English speaking population, marketing materials and election forms must be provided in the language of those individuals. In order for M+C organizations to provide beneficiaries with plan information in a culturally competent manner, we provide guidance for both developing and reviewing marketing materials through our managed care manual, marketing guidelines, and operational policy letters. M+C organizations are required to submit their marketing materials and election forms to us for review prior to distribution to Medicare beneficiaries. The Regional Offices (RO), with direction from Central Office, are involved in reviewing and approving plans' marketing materials. In carrying out these efforts, the ROs balance the M+C organizations' needs for flexibility in developing beneficiary information with our responsibility to assure that materials are compliant with the regulation and are consistent nationwide. The ROs require that information be changed if it is inaccurate, misleading, or unclear.

Our plans for standardizing beneficiary enrollment and appeals notices, including the Evidence of Coverage (EOC), involve consulting with interested parties, including beneficiary advocacy groups. We are now in the process of consumer testing the enrollment and appeals notices to ensure that the message of each notice is clearly understood by beneficiaries. (For a further discussion of cultural competency issues as they pertain to the delivery of services, see section II.C.11 below.)

Comment: Commenters suggested that information should be disclosed in a standard format or model notice, including information that must be provided upon request of the beneficiary.

Response: We agree that standardized formats for M+C beneficiary notification materials are needed. Health care information that is provided in a well-designed standardized format, using consistent, descriptive terminology, assists beneficiaries in making important decisions about their health care.

We have initiated a two-phase Marketing Material Standardization Project that includes input from the managed care industry and beneficiary advocacy groups. In Phase I, we have implemented, beginning October 15, 1999, a standardized Summary of Benefits (SB), the key pre-enrollment marketing document provided to beneficiaries, so that they can compare the same

benefits and costs across several M+C plans and original Medicare. Phase II will involve standardizing beneficiary enrollment and appeals notices. We are conducting consumer testing of these notices in preparation for the final phase of the standardization initiative.

Phase II of our standardization project includes the EOC, also known as the Subscriber Agreement and Member Contract. The EOC contains an explanation of plan benefits (covered services), member rights, and member/M+C plan contractual responsibilities and obligations. The EOC is provided to beneficiaries when they join the M+C plan and annually thereafter. As part of the standardization process for the EOC, we released a model EOC on December 1, 1999, for use in contract year 2000, that M+C organizations are required to distribute to all enrolled members by May 15, 2000. In developing the model EOC, we consulted with managed care industry representatives and beneficiary advocacy groups, and we intend to use this model as a baseline for developing the standardized EOC. The process for standardizing a document as important and comprehensive as the EOC requires adequate time for input from the industry and beneficiary advocacy groups, for public review and comment, and for implementation of the standardized document. We plan to begin standardization of the EOC in the Spring of 2000 and to complete

the process in time for the November 2001 annual election period for contract year 2002.

We also have provided guidance to M+C organizations on the manner and form for disclosing the information required under §422.111(c) upon a beneficiary's request. For example, OPL 099.081, issued on February 10, 1999, addresses appeal and grievance data disclosure requirements, and further clarifying instructions were issued in OPL 2000.114. These disclosure requirements are consistent with the reporting units for the Health Plan Employer Data and Information Set (HEDIS), the Medicare Consumer Assessment of Health Plans Study (CAHPS), and the Medicare Health Outcomes Survey (HOS). We have also issued guidance on how M+C organizations can best provide information relating to compensation for physicians, specifically incentive arrangements. The guidance includes suggested language for marketing materials as well as suggested responses for requests from beneficiaries. Again, our ROs will review these materials as part of their usual responsibilities for pre-approving beneficiary materials.

Comment: Commenters expressed concern that information concerning the number and disposition of appeals and grievances from M+C plans with low enrollment may not be statistically valid, and suggested that reporting such data could be misleading to beneficiaries. They recommended that, if an M+C organization

offers a number of different M+C plans in a single service area, the organization should report appeals and grievance data on an aggregate basis, rather than on a plan-specific basis.

Response: We assessed alternative ways to report this information and decided that the most meaningful way to report this information would be to make it consistent with the reporting unit for HEDIS, CAHPS, and the Medicare HOS. The reporting unit for these instruments is the "contract market," which implies either reporting by contract or by a market area within a contract. M+C organizations must report for each contract unless we divide the contract service area into "market areas." We will assess all contract service areas to determine whether M+C organizations must report by market area, and will notify plans as soon as possible whether they must report by market area. Further details on subdividing the contract service area into market areas can be found in OPL 099-081. The OPL also describes the data collection periods and reporting periods that have been established in order for M+C organizations to report data consistently. We and our contractors are working with M+C organizations and consumer groups to determine additional information needed to develop a national managed care appeal and grievance data collection and reporting system, with data disclosure requirements to be built into this system.

Comment: Several commenters expressed concerns over the requirement for public reporting of quality improvement results. They feared that this reporting could result in: (1) M+C organizations altering their decision making to produce competitively attractive numbers" at the expense of good patient care, or (2) the dissemination of data that could easily be misinterpreted by Medicare beneficiaries, rather than of value in facilitating informed beneficiary choice.

Response: The reporting of plan-specific quality and performance indicators is based directly on the requirements of section 1851(d)(4)(D) of the Act. Moreover, we believe that it is essential for plan comparison purposes that M+C organizations report on standardized quality measures. The standardized measures that we are requiring, as discussed in detail in section II.D of this preamble, are largely those of HEDIS. These measures are predictive of health care outcomes, well-defined, and well-established in the private sector. Thus, we do not believe that the commenters' concerns that the reporting of these measures will negatively affect M+C organizations' decision making and lead to widespread public misinterpretation are justified.

Comment: We received several comments regarding notification of beneficiaries of changes in an M+C plan's provider network. Three commenters suggested that the

requirement that written notification to the enrollee occur within 15 working days of the receipt or issuance of a notice of provider termination would be confusing for enrollees and an administrative burden for M+C organizations. Another commenter suggested that the 15 working days be converted to calendar days to be consistent with the appeals requirements under Subpart M.

Response: We recognize that the requirement that written notice be provided "within 15 working days of receipt or issuance of a notice of termination" has the potential in some situations to cause confusion for beneficiaries and impose an unnecessary administrative burden on M+C organizations. For example, because contract negotiations with providers often extend beyond a 15-day period after initial notice of termination, an M+C organization may be unable to furnish definitive network information to its enrollees within the 15-day time frame. Therefore, we are revising §422.111(e) to decouple the enrollee notice time frame from the “issuance or receipt” of a notice of termination and instead require that an M+C organization make a good faith effort to provide written notice at least 30 calendar days before the termination effective date. (As the commenter suggested, we agree that measuring this time frame by using calendar days, rather than working days, would improve the internal consistency of the M+C regulations, as well as eliminating any possible confusion over what constitutes a "working day.")

Comment: Two commenters suggested defining "regular basis" for purposes of §422.111(e). Under this requirement, a M+C organization must notify "all enrollees who are patients seen on a regular basis by the provider whose contract is terminating." One commenter suggested that "regular basis" be defined as seeing a provider within the last 180 days or 6 months.

Response: Section 422.111(e) is clear that all enrollees who are patients of a primary care professional (PCP) must be notified by the M+C organization when a PCP's contract is terminated. We are not making any change in this regard. For other providers, the regulations establish the "regular basis" standard. Generally, we would interpret this standard to require the notification of all enrollees who have a referral to a specialist for an ongoing course of treatment, or of all regular patients of an OB/GYN, for example. In combination with the explicit requirement for notification of all patients of a PCP, we believe that the "regular basis" standard is sufficient for accomplishing the objective of notifying all enrollees who are likely to be affected by a provider termination. We note that this requirement does not preclude the providers themselves from notifying M+C enrollees of the termination of their participation in an M+C plan's provider network.

11. General Access Requirements (§422.112)

a. Introduction

Section 422.112 establishes a series of requirements aimed at ensuring that enrollees in M+C plans have adequate access to services. As discussed in our June 26, 1998 interim final rule (63 FR 34989), these requirements stem from section 1852(d) of the Act and existing regulations and policies under part 417, as well as addressing recommendations from the Consumer Bill of Rights and Responsibilities, and reflecting standards from the Quality Improvement System for Managed Care (QISMC).

On February 17, 1999, we published a final rule (64 FR 7968) that set forth limited changes to the M+C regulations published in the June 26, 1998 interim final rule. In the February 17, 1999 final rule, we made changes to several of the access provisions of this section. These changes involved the coordination of care requirements, provisions related to complex or serious medical conditions, notification requirements when specialists are terminated from an M+C plan, and initial care assessment requirements.

More specifically, for serious and complex conditions, the treatment plan may be updated by a health care professional other than the primary care provider. Furthermore, this section now requires that the M+C organization ensure adequate coordination of providers for persons with serious or complex medical conditions. Under the general coordination of care requirements, the responsibility for ensuring coordination of care is not

limited to an individual provider. Instead, the organization must: 1) establish policies to ensure coordination; and 2) offer each enrollee a primary source of care. Further, as to the initial assessment, each organization will be expected only to demonstrate a "best effort" attempt to complete the assessment of health care needs within 90 days of enrollment. Finally, we no longer require, when a specialist is involuntarily terminated from an M+C plan, that the M+C organization offer to provide enrollees with the names of other plans in the area that contract with the specialist. However, as discussed above, the general requirements regarding notification of affected patients upon provider termination remain in effect. Comments on aspects of the access requirements that were not addressed in our February 17, 1999 final rule are discussed below.

b. Provider Network (§422.112(a)(1))

Section 422.112(a)(1) requires M+C organizations that wish to limit an enrollee’s choice of providers to maintain and monitor a network of appropriate providers that is supported by written agreements and is sufficient to provide adequate access to covered services to meet the needs of the population served. We received several comments regarding access standards and one comment regarding contracting with community pharmacies.

Comment: Several commenters asked us to elaborate on access standards by including time and distance travel standards, such

as specifying a 30-mile standard except where travel is difficult.

Response: Both the Medicare managed care manual and the QISMC guidelines issued on September 28, 1998 specify that a 30-mile standard must be satisfied in order to meet access requirements, except where a different standard is justified by geographic factors. We believe the inclusion of this requirement in these documents provides sufficient guidance on this subject. Furthermore, because the community pattern of care in some rural areas is to travel further than 30 miles for care, we do not believe it would be appropriate to establish an absolute 30-mile standard in the regulations.

Comment: One commenter requested that we require M+C organizations to contract with community pharmacies that are easily accessible.

Response: Community pharmacies have a number of advantages, and thus, M+C organizations should consider this as an option in providing pharmacy services. However, other options, such as pharmacy benefit management companies or mail order pharmacies, may have other advantages that are appropriate for M+C organizations to consider, such as lower cost. In choosing among these options, the M+C organizations must ensure that the providers of pharmacy services meet the various access and quality standards required by these regulations, implementing

manuals and guidelines. Given these criteria, we do not believe it appropriate to require that community pharmacies be mandated as the source of pharmacy services.

c. Primary Care Provider Panel (§422.112(a)(2))

Section 422.112(a)(2) requires an M+C organization that wishes to limit an enrollee's choice of providers to establish a panel of PCPs from which an enrollee may choose. We received two comments regarding the PCP panel.

Comment: One commenter specified that all PCPs should be licensed physicians or Doctors of Osteopathy.

Response: QISMC Standard 3.2.1.2 provides additional guidance with respect to our policies regarding PCPs. The guideline states:

> An organization may permit licensed practitioners other than physicians to serve as primary care providers, consistent with requirements of applicable State laws. (Qualifications of such practitioners, and the degree of supervision required, are generally established under State law). If an organization designates nonphysician practitioners as primary care providers, it must still ensure that each enrollee has a right to direct access to a physician for primary medical care. This right may be ensured in either of two ways: (a) the enrollee may choose between a physician and

nonphysician primary care provider, and may change this choice at any time; or (b) when the enrollee is not allowed such a choice, an enrollee with a nonphysician primary care provider may have timely access to a physician upon request.

The guideline further states: "An organization may allow an enrollee to select a physician group, clinic, federally qualified health center, or other facility with multiple practitioners as his or her primary source of care. To the extent feasible, the enrollee must be allowed to choose an individual primary care provider within the group or facility."

Thus, the QISMC guidelines do not limit enrollees to the use of physicians or Doctors of Osteopathy as PCPs. However, as indicated, an M+C organization must provide enrollees with access to physicians or Doctors of Osteopathy upon request. Furthermore, §422.112 (a)(1) requires that the M+C organization have an adequate network of providers and §422.112 (b)(2) requires the organization to offer each enrollee a source of primary care. In addition, consistent with the BBA provisions regarding antidiscrimination, and the Consumer Bill of Rights and Responsibilities, we intend to provide enrollees with freedom of choice in the selection of providers subject to the above constraints. Therefore, we are not adopting the commenter's suggestion. We note that an M+C organization's use of

nonphysicians to deliver Medicare benefits must be consistent with Medicare coverage requirements, such as "incident to" supervision requirements. To the extent nonphysicians are providing non-Medicare covered services as an additional or supplemental benefit, these requirements do not apply.

d. Specialty Care (§422.112(a)(3))

This section requires an M+C organization to provide or arrange for necessary specialty care, and gives women enrollees the option of direct access to a women's health specialist within the network for women's routine and preventive health care services, notwithstanding that the M+C organization maintains a PCP or some other means for continuity of care.

Comment: One commenter expressed concern that an M+C organization may prohibit enrollee access to a specialist without a referral from a PCP, even when not all enrollees will choose to select, or be provided, a PCP. This would effectively deny access to specialist care to such individuals.

Response: Again, all M+C organizations must provide an adequate network of providers (§422.112(a)(1)), offer to provide each enrollee with an ongoing source of primary care (§422.112(b)(2)), and provide a primary source of care to each enrollee who requests one. In addition, §422.112(a)(3) requires an M+C organization to provide or arrange for necessary specialty care. (As discussed above in section II.C.1, we are revising

§422.112(a)(3) to clarify that an M+C organization shall authorize out-of-network specialty care when its plan network is unavailable or inadequate to meet an enrollee's medical needs.) If an M+C organization requires its enrollees to obtain a referral in most situations before receiving services from a specialist, specialty care is medically necessary, and the enrollee has not selected a PCP, the M+C organization must either assign a PCP for purposes of making the needed referral or make other arrangements to provide the necessary care. Accordingly, we have revised §422.112(a)(2) to specify that the M+C organization must make specialty care available even if a plan enrollee has not selected a PCP.

Comments: Several commenters asked for clarification of the terms "routine" and "preventive" as they apply to women's health services. They asserted that routine services should include more than just preventive services, while the examples offered in the preamble to the June 26, 1998 interim final rule only were limited to preventive services. One commenter noted that there are many services that OB/GYNs are most appropriately qualified to provide that should not require a referral from another physician, such as hormonal replacement therapy, and treatment of osteoporosis, genital relaxation disorders, incontinence, abnormal uterine bleeding, urinary tract infections (UTI), and sexual dysfunction. Another commenter suggested that we clarify

that even though women have direct access to women's health specialists, it was not intended that the PCP be bypassed.

Response: We consider routine and preventive women's health care services to mean: an exam that is provided on a regular, periodic basis, in the absence of presenting symptoms, diagnosis or complaints, for disease prevention and health maintenance. The examples from the commenter, therefore, are not routine and preventive.

In the setting of such an exam, abnormalities may be found, such as incidental vaginitis or UTI, or abnormal Pap smear. We would consider routine services to follow up on such gynecologic abnormalities to be included under this definition.

We agree that the provision is unclear about the role of PCPs, and have deleted from §422.112(a)(3) the reference to "while the plan maintains a PCP or some other means for continuity of care."

Although the regulations require that M+C organizations allow women direct access (that is, without referrals or preauthorization) to a women's health care specialist within the network for women's routine and preventive services, if there is a PCP, he or she needs to be kept informed of the health care provided by such specialists. It is up to the M+C organization to develop appropriate strategies for assuring such an outcome.

We note that an M+C organization may place restrictions on enrollees as to the eligible universe of providers to whom they may "self-refer" for women's health services. Thus, QISMC guideline 2.2.3.2 provides for M+C organizations to create formal subnetworks. In these cases, an organization can require an enrollee at the time of initial selection of a PCP, to choose an entire subnetwork that may also include specialists, hospitals, or other providers. The enrollee may be required to obtain covered services, including routine and preventive women's health services through providers affiliated with the system. Under the QISMC guideline, an enrollee could change his or her choice of subnetwork at any time. (See the guidelines for further details, including an M+C organization’s responsibilities to ensure that enrollees are aware of the implications of their choice of a PCP in terms of the available subnetworks associated with a given PCP.)

Comment: One commenter suggested that we allow OB/GYN specialists to serve as PCPs.

Response: Although such a practice is permissible under the M+C regulations, we believe that this is a decision that should be made by the M+C organizations, based upon the needs of their enrollees and available resources. This position is consistent with that adopted regarding use of specialists with respect to

"serious and complex" medical conditions, as stated in the February 17, 1999 final rule.

e. Serious Medical Conditions (§422.112(a)(4))

Under §422.112(a)(4), M+C organizations must have procedures that enable the organization to identify individuals with serious or complex medical conditions, assess and monitor those conditions, and establish and implement treatment plans.

Comment: Several commenters asked for clarification of what is meant by “serious or complex medical conditions.”

Response: On August 31, 1999, the Institute of Medicine (IOM) submitted a final report to us, entitled "Definition of Serious and Complex Medical Conditions." This report is available through the Internet at "www.nas.edu".

A key recommendation made in the report is: "The committee recommends that the Health Care Financing Administration should provide *guidance* [emphasis added] to health plans to assist their efforts to identify patients with serious and complex medical conditions. Specifically, the committee recommends the following language be used to facilitate efforts of plans to identify their enrollees with "serious and complex conditions": a *serious and complex* condition is one that is persistent and substantially disabling or life-threatening that requires treatments and

services across a variety of domains of care to ensure the best possible outcomes for each unique patient or member."

In view of the committee's recommendation that it is premature to establish an administrative definition of these terms, we have decided not to make any changes at this time to the regulations regarding serious medical conditions. We will provide further policy guidance on the meaning of this definition through a future OPL. For now, M+C organizations have the option of adopting the IOM definition or developing an alternative definition.

The committee also recommended that rather than focus on access to specialists, the treatment plans that M+C organizations develop should address access to specialty care. Furthermore, the committee recommended that M+C organizations develop a care management strategy that integrates the participation of all those involved in the care of the patient, including primary care physicians; medical and surgical specialists; nurses and nurse specialists; behavioral and mental health specialists; physical, occupational, and speech therapists; social workers; allied health professionals; and community-based service providers. The forthcoming OPL will address these strategies, as well as provide guidance on implementation and monitoring procedures.

f. Written Standards (§422.112(a)(7))

Section 422.112(a)(7) (as recodified in the February 17, 1999 final rule) requires the establishment of written standards for specified areas of policy and procedures (coverage rules, practice guidelines, payment policies, and utilization management). This section is based on existing regulations and policies under part 417. We received two comments regarding this requirement.

Comment: In a comment cosigned by one hundred and fifty advocacy organizations, it was suggested that we amend the regulations regarding use of practice guidelines to specifically encourage or require contracting managed care plans to use Federally-developed practice guidelines, where appropriate.

Response: In general, we concur with the commenters that the use of Federally-developed practice guidelines, such as those produced by the Department of Health and Human Services, in the provision of services is a desirable objective. However, we believe that the commenter's suggestion that use of these guidelines be mandated by regulation would be inconsistent with section 1801 of the Act, which provides that the Medicare statute "shall [not] be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided. . . ." While we thus do not believe that mandating use of Federal guidelines is appropriate, we do encourage M+C

organization health provider committees to explicitly consider such recommendations, particularly as they relate to care of enrollees with high-risk, complex care needs (such as those with HIV disease, cancer, etc.).

Comment: One commenter requested that we specify that the "responsible health professionals" be included in the development of practice guidelines and medical review criteria.

Response: We encourage M+C organizations to include the responsible health professionals in the development of such written standards. In some cases, however, a physician may be qualified to develop standards that apply to other health professionals, and it could impose an undue burden on M+C organizations to require that all responsible health care professionals always be consulted about standards. We therefore do not believe it would be appropriate to impose an absolute requirement that all health professionals always be included in developing written practice guidelines. We believe, however, that as a general matter, it is important that health care professionals such as physician assistants, advanced practice nurses, clinical psychologists and others integrally involved and knowledgeable regarding treatment planning and delivery, contribute to the process of standard development. We would thus expect that M+C organizations generally will consult with such professionals in developing guidelines in their areas, even

though we are not imposing an absolute requirement for such consultation in all cases. For a further discussion of this issue, see the portion of the February 17, 1999 final rule dealing with provider participation rules.

g. Cultural Considerations (§422.112(a)(9))

Section 422.112(a)(9) (as recodified in the February 17, 1999 final rule) requires that services be provided in a culturally competent manner to all enrollees, including those with limited English proficiency or reading skills, diverse cultural and ethnic backgrounds, and physical or mental disabilities. We received many comments regarding this section.

Comment: Many commenters asked for clarification regarding the term "culturally competent" and our expectations with respect to the implementation and monitoring of this requirement. While some commenters asserted that the cultural competence requirement would be too burdensome and should be deleted, most supported the requirement, but requested additional detail and guidance regarding its interpretation.

Response: In reviewing the comments received, there were several recurrent themes: (1) widespread support of the general requirement that all health care services be provided in a culturally competent fashion; and (2) a need for us to clarify our expectations with respect to acceptable activities undertaken to achieve that goal.

We do not believe that changes to the regulation text regarding the definition of cultural competence are needed, other than to delete the reference in the regulations to mental and physical disabilities (as discussed below). However, in this preamble, we will attempt to provide further guidance on this issue. We also intend to incorporate the principles discussed here into the QISMC guidelines as we revise the QISMC cultural competence standards.

We believe that the delivery of culturally competent health care and services requires health care providers and administrative staff to possess a set of attitudes, skills, behaviors, and policies that enables the organization to function effectively in cross-cultural situations. Appropriate care delivery should reflect an understanding of the importance of acquiring and using knowledge of the unique health-related beliefs, attitudes, practices and communication patterns of beneficiaries and their families to improve services, strengthen programs, increase community participation and eliminate disparities in health status among diverse population groups.

Activities to promote achievement of this objective fall under a variety of categories, including but not limited what we refer to as "Organizational Readiness," "Community Assessment," "Program Development," and "Performance Improvement," for example. Under Organizational Readiness, M+C organizations would

conduct educational programs to increase the knowledge of their staff about the unique health care beliefs, attitudes, practices, and communication patterns of the populations served by their plan. Title VI of the Civil Rights Act (see 28 CFR §42.405(d)(1)) specifically requires that M+C organizations provide assistance to persons with limited English proficiency, where a significant number or percentage of the eligible population is likely to be affected. These requirements may require the organization to take some of the following steps: assess the language needs of beneficiaries in their service area, provide sufficient access to proficient interpreters, and disseminate written policies on the use of interpreters. In addition, the M+C organization provider network should be capable of meeting the cultural, linguistic, and informational needs of the beneficiaries residing in the service area. Ideally, the racial and ethnic diversity of the service area would be reflected in the provider network and staff of the M+C organization. The literature has demonstrated that enrollees are more likely to seek and accept health care services when delivered by one of their own racial or ethnic group. The M+C organization must ensure that all employees have received education regarding the importance of providing clinically competent and culturally appropriate services.

Community Assessment entails conduct of a market assessment to identify the specific health care needs of the beneficiary

population as they relate to enrollee groups' health problems (for example, some diseases are ethnically and genetically linked). Using existing and secondary data resources, organizations would collect data to the extent necessary to identify any special culturally-based health care needs among their beneficiaries. Program Development would entail implementation of formal programs and culturally sensitive patient education projects that reduce and eventually eliminate cultural, linguistic, and informational barriers known to deter or discourage health-seeking behavior.

Finally, Performance Improvement would entail addressing an identified need or opportunity for improvement, either through a quality improvement project or other formal program that seeks to resolve undesirable differences in utilization of services and outcomes of care across all relevant racial, ethnic and cultural groups served by the managed care organization.

The goal is to promote quality health care services, ensure effective dissemination of information, and enhance consumer rights and protections by fostering a demonstrated commitment to and establishing a coordinated and integrated system for, cultural competence. This approach is consistent with other Federal initiatives and recommendations from the President’s Race Initiative and from the President’s Advisory Commission on Consumer Protection and Quality in the Health Care Industry.

As achieving this objective is a M+C program requirement, M+C organizations will be monitored for compliance in this regard. We have developed additional implementation tools to assist M+C organizations in meeting the cultural competency requirement, such as operational specifications for five initial test measures and further steps which could be taken to improve, test, and expand on enrollee, disparity and standard-based inventories. The specifications for the five initial measures were developed based upon the recommendations of an expert panel and would require no new data collection on the part of the M+C organization. We will soon be offering these measures to M+C organizations for use in their QAPI projects.

Finally, ensuring culturally competent care is congruent with our commitment to being a prudent purchaser of health care services. A growing body of knowledge demonstrates that when care is provided in a clinically competent and culturally appropriate fashion, it is more readily understood and accepted by the patient. As a result, patient compliance with treatment is enhanced, outcomes are improved, and health care costs and expenses are reduced as a result of diminished morbidity and mortality.

Comment: One commenter pointed out that physical and mental disabilities are unrelated to cultural competence issues. The commenter stated that including a reference in §422.112(a)(9) to

individuals with physical and mental disabilities was insensitive and inappropriate, noting that such disabilities are not a "culture".

Response: We believe that the principle objective underlying the requirement to provide services in a culturally competent manner is to address unique racial and ethnically-related health care concerns. Thus, we agree with this commenter, and are deleting the relevant language. We note that the special concerns and rights of individuals with physical or mental disabilities are addressed elsewhere in the M+C regulations (for example, under §§422.110(c) and 422.502(h)(1)(iii)).

Comment: One commenter believes that Federal law prohibits providing material below high school reading level.

Response: We were unable to locate any statutory citation in support of the commenter's view, and none was provided by the commenter. We believe that the commenter is mistaken that materials at a reading level *below* high school cannot be provided. Market research has shown that the majority of Medicare enrollees are able to most effectively comprehend the complex issues addressed in our literature when the information is targeted for those at a 4th-6th grade reading level. The Medicare Handbook accordingly is geared for individuals at

precisely that level. Therefore, we believe that our current approach is both appropriate and well-justified.

12. Confidentiality and Accuracy of Enrollee Records (§422.118)

Consistent with section 1852(h) of the Act, §422.118 requires M+C organizations to establish procedures that safeguard the confidentiality and accuracy of enrollee records that identify a particular enrollee, including medical documents, administrative documents, and enrollment information. The regulations specify that information from these records may be released only to authorized individuals. Each M+C organization must establish procedures for complying with the confidentiality standards, including policies governing access to information within the organization as well as when and how information may be disclosed outside the organization without enrollee authorization. Additionally, the M+C organization must maintain accurate records and ensure timely access for enrollees who wish to examine their own records.

The M+C organization must abide by all applicable State and Federal laws regarding confidentiality and disclosure of health information and any other information about enrollees. In the existing regulations, "mental health records" are mentioned separately as subject to this requirement. However, because mental health records clearly constitute a subset of the other health records specified at §422.118 (that is, "medical records,

health information, and any other enrollee information"), we are revising the regulations via this final rule to eliminate the redundant separate reference. This has no effect on the substance of the requirement.

Comment: Several commenters have suggested that the industry needs one Federal standard for confidentiality, especially in light of the fact that State confidentiality laws would not be preempted unless they conflict with Federal requirements. One commenter stated that there thus could be 50 different sets of patient confidentiality standards.

Response: The M+C regulations are not the appropriate vehicle for establishing the balance between State and Federal confidentiality laws. This issue is under discussion in Congress, which is a more appropriate venue for making this determination. Further, because Federal standards for confidentiality and privacy of individually identifiable health information have recently been proposed by the Secretary (as discussed in some detail below), and because M+C organizations will be required to comply with those regulations once they are finalized, we have chosen not to make substantive changes in the existing M+C confidentiality regulations at this time. In the interests of clarification, however, we have made some technical changes in the existing requirements, including reorganizing them to (1) promote consistency with the confidentiality requirements

under other Federal health care programs (such as Medicaid) and (2) emphasize the importance of applicable Federal and State laws, while still ensuring that the privacy of M+C enrollees' health information is safeguarded in the absence of other applicable laws.

Pursuant to Section 264 of the Health Insurance Portability and Accountability Act (HIPAA) (Pub. L. 104-191), the Secretary of Health and Human Services was directed to promulgate regulations on the confidentiality and privacy of individually identifiable health information if confidentiality legislation governing electronic health information was not enacted by August 20, 1999. Such legislation was not enacted, and the Secretary published a notice of proposed rulemaking, Standards for Privacy of Individually Identifiable Health Information, in the Federal Register at 45 FR 160, et seq, on November 3, 1999. (This proposed rule is available at the Administrative Simplification web site, http://aspe.hhs.gov/admnsimp/). As proposed, these regulations would apply to health information that has been maintained or transmitted electronically, or held by health plans, health care providers who engage in certain electronic transactions, and health care clearinghouses. M+C organizations would be considered health plans for the purposes of the proposed privacy regulation. The proposed rule would

establish detailed standards for the use and disclosure of electronic health information.

Comment: Several commenters suggested that we develop procedures regarding the maintenance of confidentiality of patient records, and have said that these procedures should be provided to the beneficiary.

Response: As noted above, in light of the pending privacy regulations, we are not imposing any additional requirements here. The Secretary's proposal would require health plans (including M+C organizations) and other covered entities to develop procedures for maintaining the privacy of health information and to inform patients and enrollees of their confidentiality practices.

Comment: Several commenters asked for clarification of preamble language at 63 FR 34991, which they read to preclude M+C organizations from sharing patient information with outside contractor claims administrators without individual patient consent.

Response: The M+C regulations are not intended to prohibit the sharing of patient identifiable information within an M+C organization or between the organization and its contractors for the purposes of payment, treatment or coverage decisions. Thus, an M+C organization may circulate such information within the organization, and externally, to the extent that such information

is needed to coordinate or bill for the care of an M+C enrollee. However, M+C organizations generally are prohibited from selling or circulating patient identifiable data to outside organizations or entities that are not involved in payment, treatment, or coverage decisions, without specific authorization from the enrollee or an enrollee's authorized representative.

Comment: Several commenters asked us to specify that patient data may be shared for bona fide medical research, and to limit the extent to which patient identifiable information could be released for research purposes. One commenter asked for clarification as to whether information can be shared in the event of a court order or subpoena.

Response: As discussed above, we are not expanding on the existing M+C confidentiality requirements to address specific issues here, such as to whom and under what conditions release of patient identifiable information is authorized. To the extent that M+C organizations have proper safeguards in place and to the extent that State law authorizes the release of such information, this section of this regulation does not bar the use and disclosure of records for medical research. Section 422.118(a) expressly states that medical records may be released in accordance with "court orders or subpoenas." The Department’s proposed privacy regulation would set forth specific standards for disclosing information in both of these situations, and when

that regulation is finalized, M+C organizations will be permitted to disclose information only in accord with those standards. In the interim, M+C organizations could voluntarily use those proposed privacy standards as a guide in formulating their policies and making disclosure decisions.

13. Information on Advance Directives (§422.128)

Advance directives are documents recognized under State law, signed by a patient or his/her authorized representative that explain the patient's wishes concerning a given course of medical care should a situation arise when he or she is unable to make these wishes known. The M+C organization is legally responsible for providing enrollees with information on their rights under State law to establish advance directives, and ensuring that advance directives are documented in a prominent part of the beneficiary's medical record. The M+C organization is permitted to contract with other entities to furnish information concerning advance directives requirements. The M+C regulations retain for M+C organizations the requirements that applied to HMOs and CMPs under part 417, which state an HMO must maintain written policies and procedures concerning advance directives as defined in §489.100 with respect to all adult individuals receiving medical services by or through HMOs.

Comment: Commenters asserted that M+C organizations should not be responsible for obtaining or documenting the existence of

an advance directive, and that organizations should ensure that "responsible health care entities educate patients and document the existence of advanced directives." The commenters stated that an M+C organization cannot reasonably be held responsible for documenting whether an individual has elected an advance directive because the chart is in the control of the primary care physician.

Response: Our position that an M+C organization should be responsible for obtaining and documenting the existence of advance directives is consistent with the requirements of both State law and the Patient Determination Act of 1991, which we expanded upon in our final rule on June 27, 1995 (42 CFR §489.100). Both the Act and the regulations include managed care organizations among the entities responsible for obtaining and documenting advance directives information. The BBA made these same standards applicable to M+C organizations.

Comment: A commenter asked for clarification as to what we will accept as evidence of best efforts and reasonable plan oversight. Another commenter suggested we should require M+C organizations to submit and receive approval on all advance directive documents. This commenter feared (and alleged that there is proof) that an M+C organization might lead beneficiaries down a path of less care in times of greatest need, and that

advance directives could be used by an organization to coerce a beneficiary to forego care.

Response: The M+C advance directive requirements, which fee-for-service providers have been following for some years, are guidelines which refer to State law. Therefore, M+C organizations must comply with the advance directive requirements of the States which they serve, and we cannot give detailed guidelines as to what constitutes best efforts in each State. We believe the Medicare regulations give provider entities and States a great deal of flexibility, and we are prepared to work with them on specific entities.

Regarding the commenter's concerns about possible encouragement of inappropriate underutilization as the result of advance directives, we believe that the monitoring process will prevent and/or identify abuses of advance directives. For example, the M+C contractor interim monitoring guide states that an organization's policies must promote enrollee understanding of their conditions and facilitate the development of mutually agreed upon treatment goals. We have stated in QISMC and OPL 98-72, that with respect to advance directives, the M+C organization must meet several criteria, including that it may not make treatment conditional or otherwise discriminate on the basis of whether an individual has executed an advance directive. Underutilization patterns should be revealed by other aspects of

the monitoring process, and, with regard to advance directives specifically, we are exploring the possibility of developing further monitoring criteria.